Kentucky All Schedule Prescription Electronic Reporting (KASPER)

A Comprehensive Report on Kentucky's Prescription Monitoring Program

Prepared by the

Cabinet for Health and Family Services

Office of the Inspector General

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Table of Contents

Table of Figures

1 Purpose of this Report

This report has been prepared by the Cabinet for Health and Family Services (CHFS), Office of the Inspector General (OIG) in order to provide a detailed and comprehensive explanation of the Kentucky All Schedule Prescription Electronic Reporting (KASPER) program. KASPER is Kentucky's Prescription Monitoring Program (PMP), built around the enhanced KASPER (eKASPER) system.

This report provides information about the background and history of KASPER, the state agencies responsible for the development and maintenance of KASPER, operation and use of the system, related investigative activities performed by the Drug Enforcement and Professional Practices Branch, federal and state programs that provide funding and support for KASPER, education and training programs, the effectiveness of KASPER, a national perspective on PMPs and KASPER, and future plans and considerations for KASPER. The intent is to provide the reader with a detailed reference document covering the background and reasons for the development of KASPER, the scope of the KASPER program and how it helps address prescription drug abuse and diversion problems, and plans for future enhancements to improve the efficiency and effectiveness of the program.

The Office of the Inspector General is proud of the KASPER program and the impact it has had on addressing problems with prescription drug abuse and diversion in Kentucky. Kentucky is widely viewed as the leader in implementation and operation of a comprehensive PMP. Those wishing to learn more about KASPER are urged to review this report and contact any of the organizations and individuals associated with the program for more information. Section 12 Contact Information provides detailed contact information including the KASPER Web site and support organization names, phone numbers and e-mail addresses.

2 Problems with Controlled Pharmaceutical Substances

2.1 A National Problem

Abuse and diversion of controlled pharmaceutical substances is reaching epidemic proportions in the United States. In July 2005 the National Center for Addiction and Substance Abuse at Columbia University (CASA) published a study, *Under the Counter: The Diversion and Abuse of Controlled Prescription Drugs in the U.S.* Figure 1 illustrates the increase in controlled substance abuse compared with the increase in the U.S. population as reported by CASA.

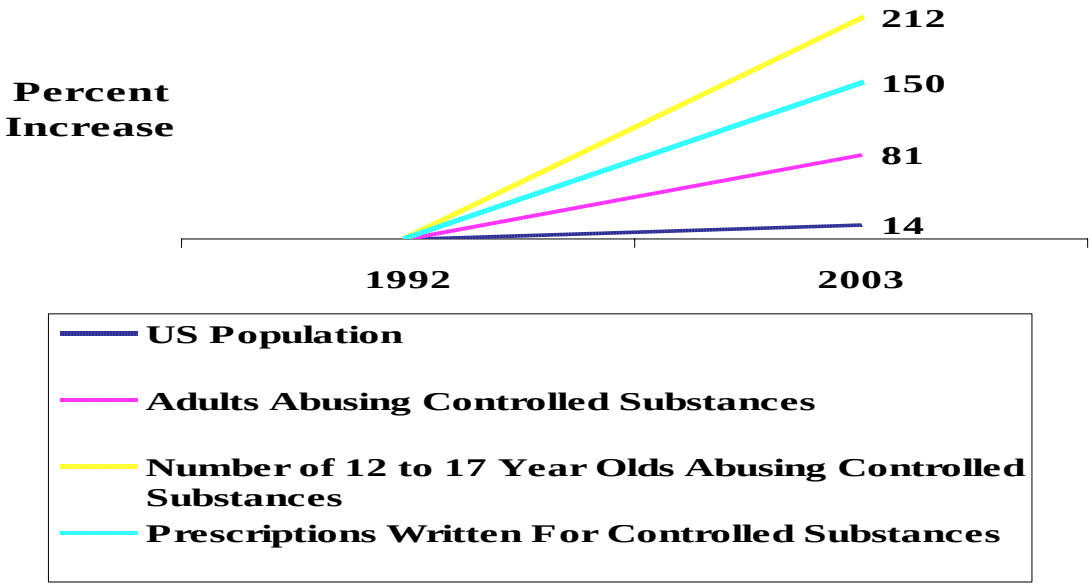


Figure 1 - Controlled Substance Abuse

From 1992 through 2003, the U.S. population increased 14%. During this period the number of adults 18 and older abusing controlled prescription drugs increased 81%, the number of 12 to 17 year olds abusing such drugs increased 212%, and the number of prescriptions written for controlled drugs increased more than 150%, almost 12 times the rate of increase in population and almost three times the rate of increase for prescriptions written for all other drugs.

The CASA study determined that from 1992 to 2003 the total number of people who admit abusing controlled prescription drugs increased from 7.8 million in 1992 to 15.1 million in 2003, a 94 percent increase—almost seven times faster than the increase in U.S. population. In addition to the alarming increase in controlled substance abuse, the CASA study revealed that in 2003, the 15.1 million Americans abusing prescription drugs exceeded the number of Americans abusing cocaine (5.9 million), hallucinogens (4.0 million), inhalants (2.1 million) and heroin (.3 million) combined.

CASA also reported that just as the number of people abusing controlled prescription drugs has been on the rise, so has the resulting increase in harm. For example, controlled prescription drug related visits to emergency departments have increased three and one-half times more than heroin related visits and four times more than visits linked to cocaine abuse. The impact of prescription drug misuse and abuse is not limited to the person abusing or addicted to prescription drugs, or even just their family. The Council of State

Governments published a report in April 2004 that indicated during 2001, the costs for prescription drug misuse and abuse were estimated to impose approximately $100 billion annually in health care costs. Law enforcement officials and substance abuse treatment providers alike report that the tax-financed Medicaid program is subsidizing drug abusers. A survey of substance abuse treatment providers in the Appalachian region which includes Kentucky, West Virginia and Tennessee, reported that more and more clients use public insurance programs, like Medicaid, to get "legal" drugs to feed their addictions. This has serious implications for the Medicaid program, which cost states more than $110 billion in fiscal year 2003. In fact, fraud contributes to a $1 billion loss annually in Medicaid spending on prescription drugs.[1] The abuse and diversion of prescription drugs affects all of us in higher medical care and law enforcement costs.

One of the Recommendations from the CASA study was that the U.S. Department of Justice and the Food and Drug Administration should fund the development of model state legislation for state Prescription Monitoring Programs (PMPs) and provide financial incentives for states to develop and operate PMPs in accordance with national standards. The CASA study also recommended training of law enforcement professionals (including state and local police and prosecutors) to better understand therapeutic uses of controlled prescription medications and conditions under which the medical community recommends their use in treating patients.

As will be discussed in subsequent sections of this report, in the 1990s Kentucky officials began to realize the scope of the prescription drug abuse and diversion problem in the state, and recognized the need for this type of Prescription Monitoring Program. In 1999 Kentucky was in the forefront of implementing a PMP system and conducting training on the use of the system to support the health care and law enforcement communities in beginning to address the prescription drug abuse and diversion problem.

2.2 The Controlled Substance Problem in Kentucky

The abuse and diversion of controlled pharmaceutical substances are recognized by law enforcement and health agencies throughout Kentucky as an increasing threat. Some counties in eastern Kentucky lead the nation in terms of grams of narcotic pain medications distributed on a per capita basis.[2]

Misuse, Abuse and Diversion

There are three ways that controlled pharmaceutical substances can be used in a manner for which they were not intended; misuse, abuse and diversion. Following is a description of these uses.

Misuse is when a Schedule II – V substance is taken by an individual for a non-medical reason.

Abuse is when an individual repeatedly takes a Schedule II – V substance for a non-medical reason.

Diversion is when a Schedule II – V substance is acquired and/or taken by an individual for whom the medication was not prescribed.

Prescription Drug Abuse

The abuse of pharmaceuticals including OxyContin® (oxycodone), Xanax® (alprazolam) and methadone has reached alarming levels. The abuse of oxycodone products in particular has become so prevalent it is described by some as an epidemic. In July 2002 the National Drug Intelligence Center, an organization within the U.S. Department of Justice, reported that from 1998 through 2000 treatment for the abuse of

[1] The Council of State Governments, Trends Alert; *Drug Abuse in America – Prescription Drug Diversion*, April 2004.
[2] U.S. Drug Enforcement Administration Web site, DEA Briefs & Background, *State Fact Sheet – Kentucky 2005*

prescription drugs accounted for 20 percent of all treatment admissions in the state, and the number of patients seeking treatment for oxycodone addiction increased 163 percent. The Kentucky State Police report that OxyContin® is more popular than cocaine in eastern portions of the state. However, oxycodone is not the only problem. Three eastern Kentucky counties had enough hydrocodone (Lortab®, Lorcet® and Vicodin®) pills in 2001 to provide every adult in those counties with 156 pills. Those three counties also had more driving under the influence (DUI) arrests for drugs than for alcohol. From 1997 to 2001, eastern Kentucky court cases involving possession and trafficking in controlled substances increased 348 percent.

Doctor Shopping

One way in which individuals obtain controlled substances for abuse is "doctor shopping". Doctor shopping (also called provider shopping) is the term used to describe when controlled pharmaceutical substances are acquired by deception. Acts related to attempting to obtain a controlled substance, a prescription for a controlled substance or administration of a controlled substance, prohibited under KRS 218A.140 include:

- Knowingly misrepresenting or withholding information from a practitioner,
- Providing a false name or address,
- Knowingly making a false statement,
- Falsely representing to be authorized to obtain controlled substances,
- Presenting a prescription that was obtained in violation of the above, and
- Affixing a false or forged label to a controlled substance receptacle.

Appendix A.1 Typical Doctor Shopping Patient Behaviors identifies some typical behaviors associated with controlled pharmaceutical doctor shopping.

Prescription Drug Diversion

The increased level of diverted pharmaceutical substances has also become significant. Diversion investigations have progressed from individual abusers or addicts to small enterprises involving several people. These groups may recruit known or potential patients and transport them to several doctors across many communities to conduct large-scale doctor shopping sprees. It is not uncommon for spouses or domestic partners to work together to commit prescription drug fraud and sell the drugs. Pharmaceutical diversion now involves huge profits and large quantities of drugs being diverted from legitimate sources. Prescription drugs are diverted in several ways, including fraudulent prescriptions, pharmacy burglaries, armed robberies, employee theft, and doctor shopping.[3] Investigative agencies in Kentucky also target physicians who prescribe medication to abusers who "doctor shop". These physicians often overcharge the Medicare and Medicaid programs as well as private insurance agencies. The "patients" sell the controlled substances on the street for enormous profits, as well as abusing the substances themselves. One example of provider diversion participation is when a prescriber provides a larger prescription than is necessary and requests that the patient return part of the medication, without a legitimate medical purpose. Appendix A.2 Typical Behaviors of Diverting Providers list some typical behaviors associated with health care providers who are participating in controlled pharmaceutical diversion.

Drug Diversion Economics

Street values of prescription drugs reflect one reason why diversion has become such a problem. The following table lists estimated street values for several of the most diverted prescription drugs.

[3] National Drug Intelligence Center; *Kentucky Drug Threat Assessment*, July 2002.

Generic Name	Brand Name	Brand Cost/ 100	Street Value Per 100
Acetaminophen w Codeine 30mg	**Tylenol #3**	**$56.49**	**$800.00**
Diazepam 10 mg	**Valium 10 mg**	**$298.04**	**$1,000.00**
Hydromorphone	**Dilaudid 4 mg**	**$88.94**	**$10,000.00**
Methylphenidate	**Ritalin**	**$88.24**	**$1,500.00**
Oxycodone	**Oxycontin 80 mg**	**$1,081.36**	**$8,000.00**

Figure 2 - Street Values of "Legal" Drugs

Help for Prescription Drug Abuse

Appendix B. Prescription Drug Abuse – Questions and Support Resources was developed by the KASPER team as part education and training efforts for the public. This appendix includes questions and answers about prescription drug abuse, a test to help identify when someone may be suffering from prescription drug addiction or abuse, and resources for information and assistance.

3 Background and History of KASPER

3.1 Prescription Monitoring Programs

Prescription Monitoring Programs are designed to help prevent and detect the diversion and abuse of pharmaceutical controlled substances, particularly at the retail level where no other automated information collection system exists. States that have implemented Prescription Monitoring Programs have the capability to collect and analyze prescription data much more efficiently than states without such programs, where the collection of prescription information requires the manual review of pharmacy files, a time-consuming and invasive process. The increased efficiency of Prescription Monitoring Programs allows for the early detection of abuse trends and possible sources of diversion.

The purpose of these programs is to enhance the capacity of regulatory and law enforcement agencies to collect and analyze controlled substance prescription data by building a data collection and analysis system at the state level, enhancing existing programs' ability to analyze and use collected data and facilitates the exchange of collected prescription data among states. The data can also be made available to health care providers as a tool to assist them with patient treatment.

Currently 21 states have implemented some form of PMP. Differences among PMPs include restrictions on who may be authorized to access the data (e.g., some states limit to law enforcement only), and the scheduled controlled substances covered (e.g., some states include schedule II drugs only; some such as Kentucky include schedules II – V). Figure 3 identifies those states that currently have implemented a PMP, and Appendix C. Status of State Prescription Monitoring Programs contains some basic PMP status information for each state including ownership of the program, schedules covered, and whether they have obtained Hal Rogers Grant funding.

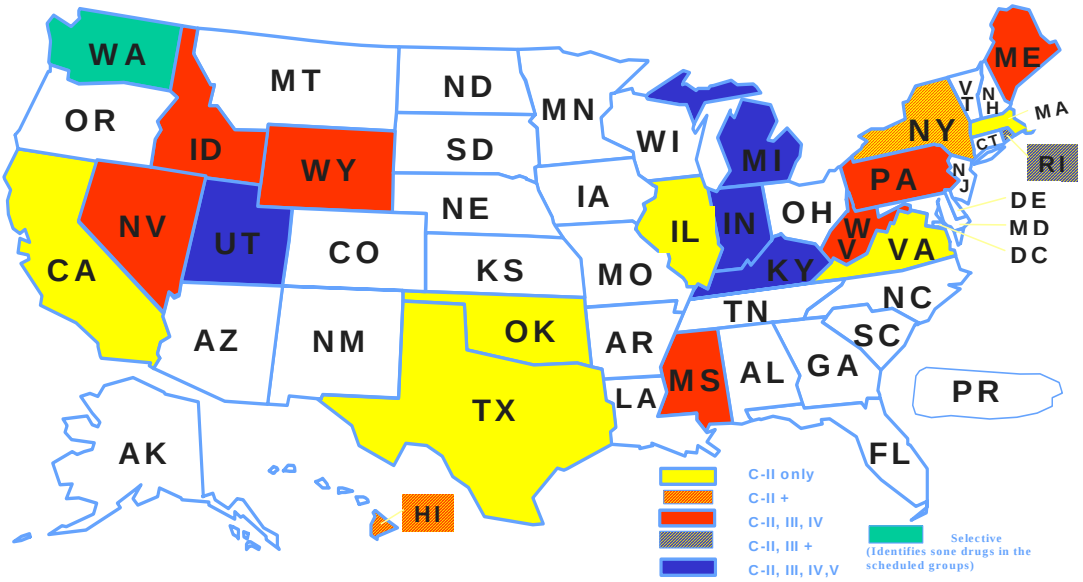


Figure 3 - States with Prescription Monitoring Programs

3.2 The Origin and Development of KASPER

Based on the scope of the prescription drug abuse and diversion problem identified in the mid 1990's, the Kentucky Attorney General in 1997 created a drug abuse task force chaired by Dr. Rice Leach, then Commissioner of the Department for Public Health, within the Cabinet for Health Services. The task force recommended that a prescription monitoring program be created as a public health initiative. The following sections describe the legislative actions and development efforts that have resulted in the current KASPER program. Appendix D. KASPER Timeline contains a graphical representation of the development and support effort leading up to the enhanced KASPER system (eKASPER).

Development of the Original KASPER System

On July 15, 1998 the Kentucky Legislature passed Kentucky Revised Statute 218A.202 directing the establishment of an electronic system for monitoring controlled substances and establishing penalties for illegal use of the system. Following passage of KRS 218A.202, work began on development of the KASPER system. On January 1, 1999 data collection from dispensers was initiated, making Kentucky one of the first states to require pharmacies and other prescription drug dispensers to report data on all schedule II – V drugs dispensed. The original Kentucky All Schedule Prescription Electronic Reporting (KASPER) system was developed during the first half of 1999 by the Governor's Office of Technology and the Drug Enforcement and Professional Practices Branch within the Cabinet for Health Services.

The data collection component of KASPER is based on KRS 218A.202 and defined in the Kentucky Administrative Regulations promulgated on December 16, 1998. 902 KAR 55:110 Monitoring system for prescription controlled substances, currently requires dispensers of controlled substances in the Commonwealth to report dispensing of Schedule II, III, IV and V controlled substances every 16 days. Kentucky has a contract with a data collection company, Atlantic Associates, to collect the batch records from each dispenser, check the validity of field formats within the record, then combine the batch records and send them to the KASPER program within 14 days. The collection and processing times result in KASPER data that is 30 – 45 days old. (CHFS is currently investigating potential processes for capturing controlled substance prescription data real-time. Refer to section 7.3 eKASPER System Upgrade (Phase II) Project for more information.)

The reporting component of KASPER was designed as a paper and fax based system. Authorized users could mail or fax a report request form to the Drug Enforcement and Professional Practices Branch. Staff members would review and process the request against the data collected from dispensers, and produce the KASPER report. The KASPER report would then be faxed back to the authorized requestor. The KASPER system and initial staffing levels were based on an estimate of approximately 2000 report requests per year.

KASPER was designed to provide a tool for use by health care professionals and law enforcement officials to fight abuse and diversion of prescription drugs. The KASPER reports are available to practitioners, pharmacists, law enforcement, professional licensure boards, Medicaid departments, grand jury subpoenas, and by court order. Figure 4 illustrates the system flow of the original paper based KASPER system.

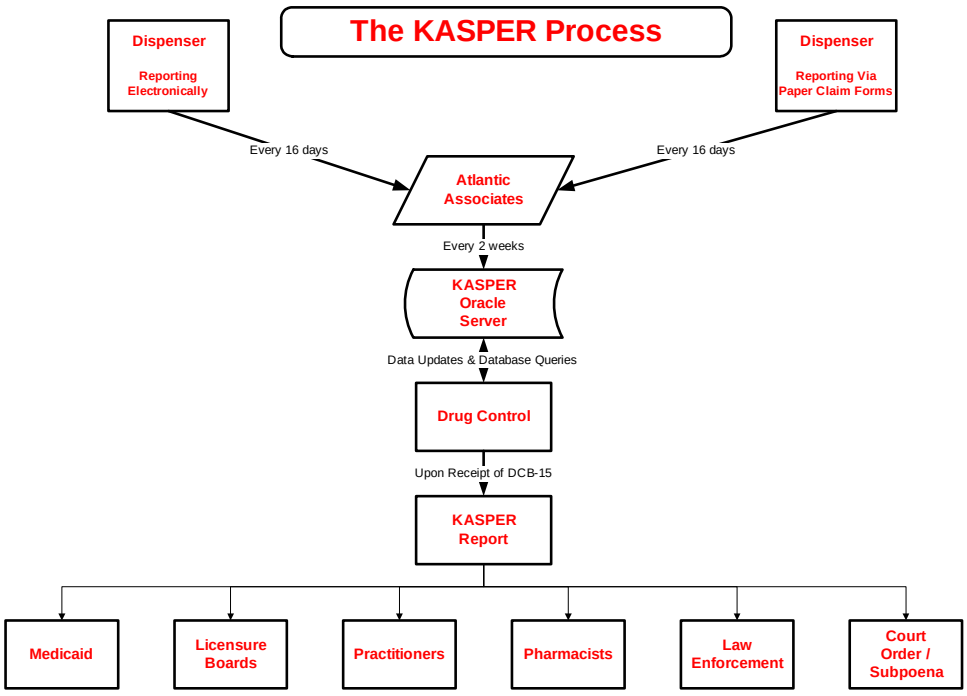


Figure 4 - The Original KASPER System Flow

Demand for KASPER Reports

KASPER was originally designed to produce approximately 2000 reports per year. By the end of 1999 over 3000 reports had been produced. Figure 5 highlights the growth in the number of KASPER reports produced during subsequent years.

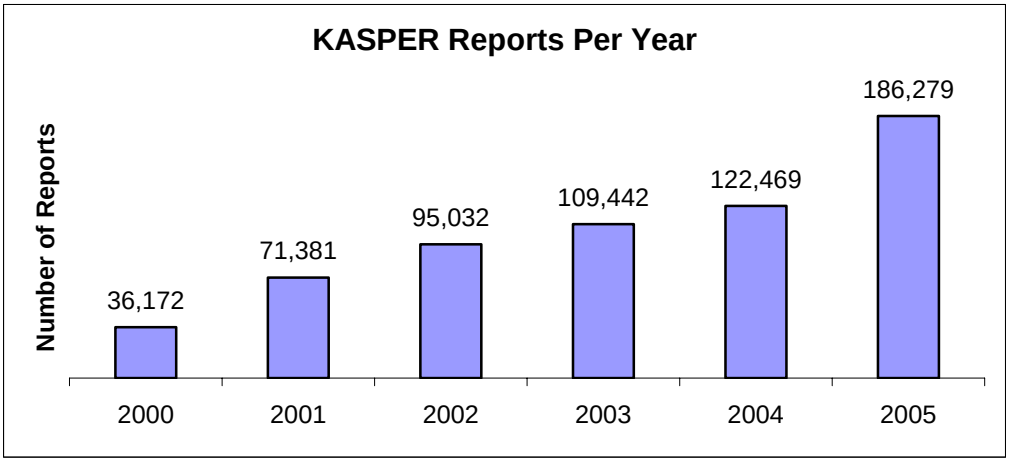


Figure 5 - The Number of KASPER Reports Produced per Year

Although KASPER had an immediate impact on the ability to monitor and control drug diversion (the average age of "doctor shopper" cases under internal investigation dropped from 156 to 19 days in 1999), the manually intense system of paper requests and faxed responses, the small number of staff members, and the unanticipated demand for KASPER reports made it difficult to provide data to requestors in a timely manner to maximize the efficiency of their processes. In 2001 requestors began experiencing delays in receiving reports. The KASPER program became backlogged with paper requests for reports, to the point where the Drug Enforcement and Professional Practices Branch investigators were logging requests and faxing reports rather than analyzing data and conducting investigations of illegal drug diversion. By June 2004, the KASPER staff was approximately six months behind in processing many KASPER report requests. Many health care practitioners were no longer requesting reports due to the processing delays.

Reorganization of KASPER under the Office of the Inspector General

In 2004 the Drug Enforcement and Professional Practices Branch (DEPPB) moved from the Division of Adult and Child Health within the Department for Public Health, to the Division of Fraud, Waste, and Abuse Identification and Prevention within the Office of the Inspector General (OIG). The unanticipated demand for reports from the system rapidly outpaced the resources available to produce the reports, resulting in a large backlog of report requests. The backlog was eroding a great deal of the good will built up from the funded enhancements and changes to the KASPER statute from the previous legislative session. The OIG concentrated scarce resources on KASPER (including permanently transferring an administrative position from the Third Party Recoveries & Cost Avoidance Section to the Drug Enforcement and Professional Practices Branch) and hiring some temporary staff. With these changes the OIG was able to eliminate the backlog and improve the "paper and fax" system to reduce report turnaround time to less than one business day in most cases, and as little as one hour at times. These efforts allowed the pharmacy administrative and investigative staff within the DEPPB to return to the investigation side full time and re-focus efforts on illegal drug diversion, armed with an improved and quicker response KASPER system. However health care professionals and law enforcement officials continued to make clear that real time access to the data was their number on priority in improving the system.

Development of eKASPER

In 2003 the Kentucky Legislature convened a Legislative Prescription Drug Abuse Task Force to study the KASPER system and make recommendations regarding improvements. The task force recommended changes that became SB14 which was passed July 13, 2004. SB14 amended KRS 218A.202 to expand the ability to share KASPER data with licensure boards, among law enforcement agencies, between law enforcement and Medicaid, and with other states. SB14 also required the Cabinet for Health Services to establish programs for continuing education related to the electronic reporting system and to work with the licensure boards to develop criteria and generate trend reports. Prior focus groups of KASPER users indicated that practitioners, the most frequent users of KASPER, wanted the ability to obtain a KASPER report any time of day, and while the patient was in the office. To address the requirement for faster turnaround of reports and the changes recommended by the task force, in 2003 the legislature appropriated $1.4 million to enhance the KASPER system. This appropriation was directed toward creating a Web-based version of KASPER to provide real time access to the data. Development of the enhanced KASPER (eKASPER) system began in 2003.

The vision for eKASPER was to create a system to allow authorized users to request a report through the Internet 24 hours per day 7 days per week, and receive the report in real time (a 15 minute response goal), while continuing to allow them to request through the mail or by fax as they do now. If the request is received through the Internet, the requestor will be validated against a database of authorized users, data from the request will be matched automatically with KASPER data and a report will be provided to the requestor within 15 minutes. Electronic requests would not be printed in order to save costs associated with paper and toner. The request form would be stored in an electronic format to save the cost of archiving paper

records. Accordingly, the greater the use of the eKASPER system, the greater the savings. The eKASPER system was developed by a team including the Cabinet for Health and Family Services Office of Information Technology, and the Drug Enforcement and Professional Practices Branch. Development and testing of eKASPER were completed during 2004 and early 2005. On March 16, 2005 the Cabinet launched eKASPER. eKASPER provides Web-based real time access to reports, while still allowing for paper requests under the original system.

As an example, an emergency room physician who has obtained a userid and password through the user validation process is now able to log onto the Web system using a secure password and request information for a patient on a 24 hours per day, 7 days per week basis. Within minutes, often seconds, a notice will appear in the physician's inbox that the report is ready for review. This can now be done while the patient is present with the physician, increasing the ability of the physician to provide better medical care and prevent abuse. Emergency room physicians could not effectively utilize KASPER reports under the original system because the questionable patients were often gone by the time a report could be made available. Also, a pharmacist who is presented with a questionable prescription can now access a report while the customer is in the store. The ability of the practitioner and pharmacist to provide quality health care and prevent abuse is significantly enhanced. Law enforcement officials and regulatory board professionals investigating prescription drug diversion cases are now more efficient by accessing a single comprehensive report in minutes, showing all relevant scheduled drugs dispensed to a suspect. Such a system provides relief to an area where law enforcement resources are desperately needed, at the same time making Kentucky a safer environment for all our citizens.

The Impact of eKASPER

The eKASPER system has been recognized at both the state and federal level as a leading edge tool to assist health care and law enforcement in the fight against prescription drug abuse and diversion. Since the launch of eKASPER in March 2005, over 1,900 health care professionals and law enforcement officials have become authorized users of the Web-based system. The number of KASPER reports produced increased 52% from 2004 to 2005. Much of this increase is attributable to the ease of use and more timely report availability through eKASPER, especially for pharmacists and emergency department physicians, who could not wait for a paper report to be faxed to them under the original KASPER system. With eKASPER they can obtain a report while the patient is in their presence, often in 15 seconds or less.

Increasing usage of eKASPER has not only allowed DEPPB staff members to focus more of their attention on investigative activities rather than report generation, but has also provided DEPPB staff with time to help identify and guide development of enhancements to the eKASPER system.

Kentucky is currently the only state with a PMP system of this scope, which has prompted multiple states to send representatives to meet with OIG and DEPPB staff members to review and discuss the KASPER program, implementation of eKASPER, and the success of the program. Several states have expressed interest in possibly obtaining the eKASPER software as a basis for their PMP implementation efforts. Future plans for eKASPER are discussed in more detail in section 11 Future Plans and Considerations on page 81.

4 The KASPER System

4.1 System Overview

KASPER tracks Schedule II – V controlled substance prescriptions written and dispensed within the state. KASPER is used by health care providers to help identify patients who may be at risk for prescription drug abuse and to verify compliance with a treatment regimen established by the patient's health care team. It is also used as a tool for law enforcement and regulatory officials during bona fide investigations and other appropriate reviews. KASPER is not designed to prevent patients from obtaining prescription drugs or to decrease the number of doses dispensed. KASPER provides real time access to data that is 30 to 45 days old, based upon the current dispenser reporting regulations. Authorized users may request reports by fax or via the secure Web application eKASPER. Via eKASPER, reports are available 24 hours a day, 7 days a week. In most cases health care professionals can receive most of their reports within 30 seconds; however occasionally a report must be manually reviewed by the KASPER staff. In those cases, the requestor is notified and will receive the report the next business day.

4.2 KASPER Data Collection and Data Availability

KASPER is currently described as providing real-time access to data that is 30-45 days old. In 2001, the Cabinet for Health Services (now CHFS) developed a strategy to improve KASPER, based upon discussions with practitioners, pharmacists and law enforcement. The strategy was documented in a white paper that listed the following priorities:

- 24 x 7 availability of reports,
- faster response to report requests,
- ongoing analysis of KASPER information
- improved data collection cycles, and
- ability to share information among authorized agencies.

In 2001 practitioners represented 87% of the KASPER report requests (currently practitioners request over 90% of KASPER reports). The practitioners identified the following requirements:

- they wanted the ability to obtain a report any time of day,
- they wanted the report while the patient is in the office,
- they tended to look for patterns of behavior that occur repeatedly over time, and
- they believed that online access to reports was a higher priority than collecting more current information.

Law enforcement also indicated that having access to the history of a patient's controlled substance prescriptions was a more important factor than real-time data in identifying doctor shoppers and drug diverters. Based upon this user input and the results of the 2003 Legislative Prescription Drug Abuse Task Force, it was determined that providing users with real-time access to the data in KASPER constituted the highest enhancement priority.

Data Collection

The collection of controlled pharmaceutical prescription data is currently based upon dispensing of the prescription. KRS 218A.202 requires that every dispenser in the Commonwealth or any other dispenser who has obtained a license, permit, or other authorization to operate from the Kentucky Board of Pharmacy shall report to CHFS the data required in a timely manner as prescribed by the CHFS except that reporting shall not be required for:

(a) A drug administered directly to a patient; or
(b) A drug dispensed by a practitioner at a facility licensed by the cabinet provided that the quantity dispensed is limited to an amount adequate to treat the patient for a maximum of forty-eight (48) hours.

As a result of this reporting requirement, almost all controlled substance prescriptions dispensed in Kentucky are entered into KASPER. 902 KAR 55:110 defines the specific data that must be reported by each dispenser and the acceptable data formats (refer to section 6.3 Title 902 Kentucky Administrative Regulation 55:110).

The data must be reported to the data collection agent designated by CHFS within 16 days of the date of dispensing unless CHFS grants an extension, typically in a situation where the dispenser experiences some type of system problem that prevents data transmission. Dispensers currently transmit their data to Atlantic Associates, Inc. the data collection agent utilized by CHFS. A small number of dispensers that do not have electronic transmission capability submit their data via hardcopy forms. Atlantic Associates validates the prescription data records by eliminating duplicate records and verifying accurate field formats against error tolerance rates established by CHFS. Data transmissions that do not meet the error tolerance rates are returned to the dispenser to be corrected and retransmitted. Atlantic Associates transmits the validated data to CHFS every 2 weeks. CHFS then loads the data into the KASPER database where it is available for access by authorized users.

This process results in the prescription data being available in KASPER approximately 30-45 days after the date of dispensing. KASPER currently collects approximately 8 million prescription records per year. Figure 6 identifies the top prescribed controlled substances in Kentucky from January 1, 1999 through July 31, 2004, by therapeutic category by doses.

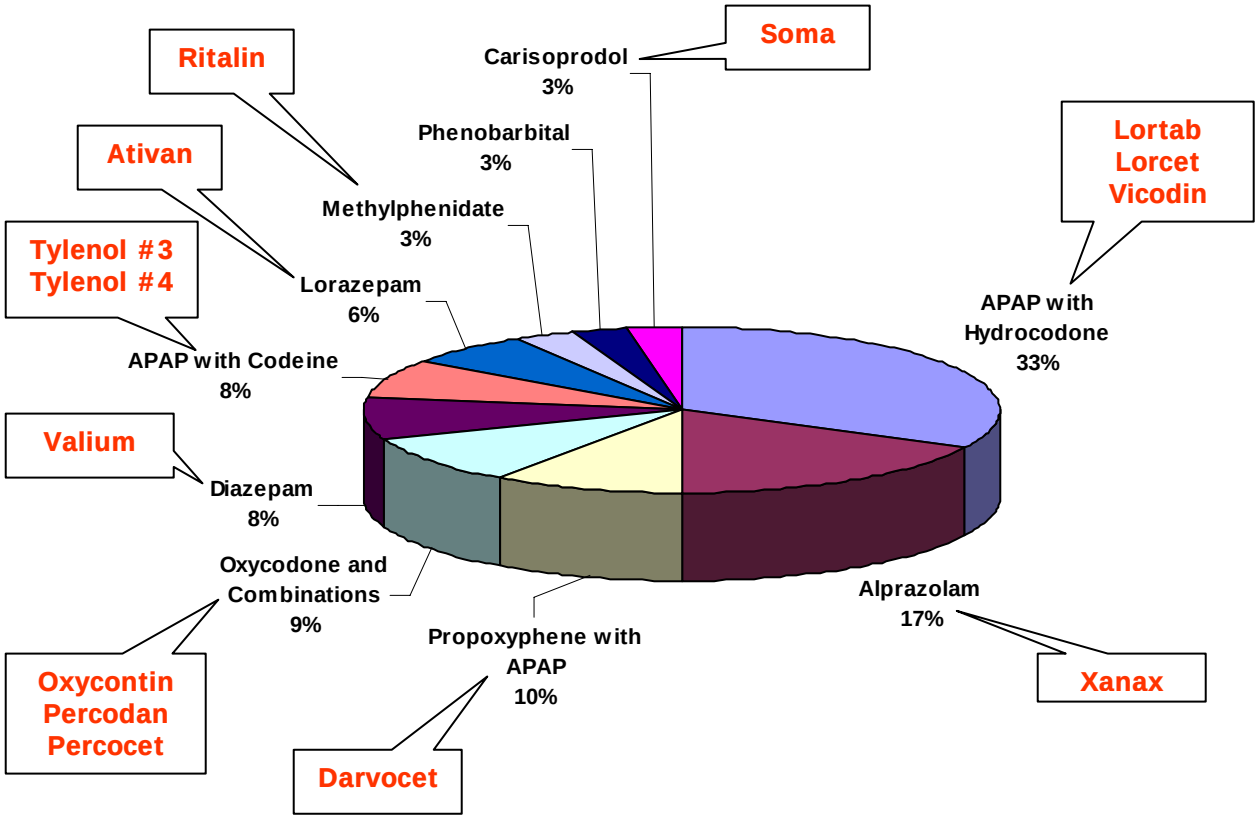


Figure 6 - Top Prescribed Controlled Substances by Therapeutic Category by Doses

Data Availability

KASPER was originally designed as a paper and fax based system, where an authorized user could mail or fax a report request to the Drug Enforcement and Professional Practices Branch, which would process the request and fax back the report. Based upon the labor intensive process, the small number of staff members available to process reports and the unanticipated demand for KASPER reports, the original system became backlogged with requests. Based upon practitioner requirements for improved turnaround of KASPER reports, and to address recommendations by the 2003 Legislative Prescription Drug Abuse Task Force, in 2003 the legislature appropriated $1.4 million to enhance the KASPER system. This appropriation funded development of the Web-based version of the system called enhanced KASPER (eKASPER). Implementation of eKASPER in March 2005 achieved the objective of providing practitioners, pharmacists and law enforcement with real-time access to KASPER reports. Real-time access to the data has been met with enthusiasm from the user community, especially from pharmacists and emergency room physicians who could not typically wait a day for a KASPER report, but needed the report while the patient was there in the pharmacy or ER. Currently 90% of KASPER reports are requested via eKASPER.

With real-time access to KASPER data now available, CHFS is pursuing the recommendation from KASPER users and from the Hal Rogers Grant Technical Specifications Working Group to investigate ways to achieving real-time data collection as well. These efforts include proposed legislation changes as described in section 6.4 Proposed Regulation Changes – 902 KAR 55:110, and investigating the possibility of utilizing a data switching vendor to capture a significant number of controlled substance prescriptions in real-time as described in section 7.3 eKASPER System Upgrade (Phase II) Project.

4.3 Users of the KASPER System

According to KRS 218A.202 (6), the Cabinet is authorized to provide KASPER data to the following:

a) Prescribers for medical treatment, and dispensers for pharmaceutical treatment for a current patient,
b) Law enforcement officers for a bona fide drug related investigation,
c) Licensure boards for an investigation of a licensee,
d) Medicaid for utilization review on a recipient,
e) Grand jury by subpoena, and
f) Court order by a judge of competent jurisdiction.

The following figure identifies the percentage of KASPER report requests by type, for the period January 1, 1999 through December 31, 2004.

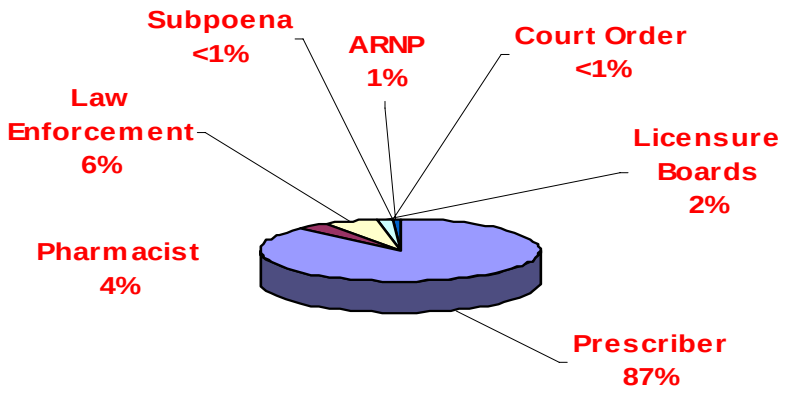


Figure 7 - Percentage of Report Requests by Type

4.4 KASPER Report Contents

KASPER patient reports show the following:

- Date range for the report,
- Patient name and date of birth,
- Prescription information such as date filled, quantity, and days supply,
- Doctor name and city,
- Drug name and strength, and
- Pharmacy name and city.

KASPER reports for law enforcement show the following:

- Date range for the report,
- Patient name, date of birth and address,
- Prescription information such as date filled, quantity, days supply and prescription number,
- Doctor name, degree and city,
- Drug name, strength and NDC number, and
- Pharmacy name, address, city and phone number.

4.5 Allowable Usage of KASPER Reports and Data

The Cabinet has implemented rigorous controls on access to KASPER, including processes to verify user identity and credentials. In addition, the Cabinet's education and training efforts continue to focus on allowable usage of KASPER reports and data. KRS 218A.202 provides that knowing disclosure of transmitted KASPER data to a person not authorized to obtain the information is a Class D felony.

Health Care Providers

A prescriber or dispenser may discuss the information in a KASPER report with:

- The patient for whom the report was generated,
- Another health care provider treating the patient,
- The dispenser who dispensed the medications, or
- Law enforcement if requested by the law enforcement officer or if the health care provider suspects criminal activity.

While the information in the report may be discussed, a health care provider or any other authorized user may not share the actual report with anyone including the patient, unless specifically authorized by KRS 218A.202.

Law Enforcement Officials

A law enforcement officer may share the information contained in the report and/or the report with other law enforcement officers as long as they are involved in a bona fide drug related investigation pertaining to the subject of the report, and required logs are maintained.

Trend and Research Data

KRS 218A.240 provides that the Cabinet shall use the data compiled in KASPER for investigations, research, statistical analysis, and educational purposes, and shall proactively identify trends in controlled substance usage and other potential problem areas. The Cabinet is currently working with the Kentucky licensure boards and the Kentucky Office of Drug Control Policy to develop standard trend reports and processes authorized organizations to request ad hoc trend reports. A set of standard trend reports will be published quarterly on the KASPER Web site. The statute requires that no trend report shall identify and individual prescriber, dispenser, or patient. (Refer to section 7.2.2.10 Develop Trend Reports for more information.)

4.6 KASPER Information Safeguards

Authorized users must apply for an account and provide supporting documents to verify their identity and credentials. All user information is verified by the KASPER staff. KASPER report requests received via fax are reviewed and prepared by KASPER staff pharmacists. Report requests received from the Web are automatically generated but are forced to a review by a KASPER staff pharmacist if:

- The report is longer than six pages,
- The report contains multiple dates of birth, or
- The report contains more than one last name.

These safeguards help ensure the data included in the report are accurate and apply only to the individual for whom the report was requested. The KASPER system includes financial institution level security features and is compliant with HIPAA and KRS 218A.202. Any violation or breach of access or usage guidelines will result in the Office of the Inspector General initiating an internal review to verify the breach or misuse, and refer the information to the Kentucky State Police for appropriate action.

4.7 KASPER Usage by Medicaid

Medicaid spending has become an issue of major concern at both the state and federal level. State governments must constantly seek ways to reign in Medicaid spending on health care, while continuing to provide necessary medical care to those in need. This requires that an emphasis be placed reducing the amount of money lost to Medicaid abuse and fraud. Much of the Medicaid abuse and fraud in Kentucky is related to abuse and diversion of controlled substance prescriptions.

Recognizing the importance of investigating and reducing Medicaid prescription drug fraud, the Kentucky legislature specified in KRS 218A.202, that KASPER data may be provided to the state operated Medicaid program. The Department for Medicaid Services may use the KASPER data and reports from KASPER for the purposes of identifying Medicaid recipients whose usage of controlled substances may be appropriately managed by a single outpatient pharmacy or primary care physician. In addition, the Department for Medicaid Services may share the data or reports regarding overutilization by Medicaid recipients with an authorized regulatory board or with an authorized law enforcement officer. The Department for Medicaid Services may also submit the data as evidence in an administrative hearing held in accordance with KRS Chapter 13B. Kentucky is the only state that provides statutory authority for the Medicaid program to utilize data from a Prescription Monitoring Program. This provides the Department for Medicaid Services the ability to be more efficient and proactive in detecting and addressing situations of prescription drug abuse or diversion by Medicaid recipients.

In addition to allowing selected Medicaid personnel to become authorized users of KASPER and to obtain KASPER reports, the Hal Rogers Grant working groups and the Office of the Inspector General determined that an automated interface between KASPER and the Pharmacy Benefit Management system utilized by the Department of Medicaid Services, would provide a significant opportunity to analyze controlled substance prescription data collected within each system, and to identify patients demonstrating a high potential for prescription drug abuse and/or fraud. Refer to section 7.2.2.6 Develop and Test a Medicaid/eKASPER Interface (MeKI) Prototype for a description of the prototype development effort, and to section 11.2 Implement a Medicaid/eKASPER Interface for a discussion of the planned interface.

5 The Organizations Responsible for KASPER

5.1 Office of the Inspector General

The Cabinet for Health and Family Services' Office of the Inspector General (OIG) is Kentucky's regulatory agency for licensing all health care facilities, day care facilities, long-term care facilities, and child adoption/child-placing agencies in the commonwealth. The OIG is responsible for the prevention, detection and investigation of fraud, abuse, waste, mismanagement and misconduct by the cabinet's clients, employees, medical providers, vendors, contractors and subcontractors. The OIG also conducts special investigations as requested by the secretary, commissioners, or office heads within the cabinet into matters related to the cabinet or its program. The Office of the Inspector General mission and vision statements are:

Mission Statement: "To protect the health, safety and well-being of Kentucky Citizens and ensure the integrity and accountability of Cabinet for Health and Family Services programs through proactive leadership and independent review."

Vision Statement: "To be a leader in protecting the health, safety, and well-being of all Kentucky Citizens through a systematic approach to preventing fraud, waste and abuse and ensuring regulatory compliance within all Cabinet Programs."

The OIG has identified the following Critical Success Factors as part of the Cabinet for Health and Family Services 3 Year Strategic Plan.

- Strengthen internal programs and services.
- Enhance service delivery systems that are customer focused and promote high quality of outcomes.
- Improve access to OIG services.
- Prevent, detect & reduce waster, fraud and abuse.

An organization chart for the Office of the Inspector General is shown in Appendix E.1.

5.2 Division of Fraud, Waste and Abuse Identification and Prevention

Located within the Office of the Inspector General, the Division of Fraud, Waste and Abuse Identification and Prevention (DFWAIP) is responsible for planning, developing and directing agency efforts to identify and prevent abuse and/or misuse in the Medicaid program. Prior to the reorganization that moved the Drug Enforcement and Professional Practices Branch and the KASPER program into DFWAIP, the division was the Program Integrity Division within the Department for Medicaid Services. DFWAIP responsibilities include verifying that medical services are appropriate and rendered as billed, that services are provided by qualified providers to eligible recipients, that payments for those services are correct, and that all funds identified for collection are pursued. The Division's focus is on the administrative/civil side of fraud and abuse.

Federal regulations require the State Plan for Medical Assistance to provide for the establishment and implementation of a statewide surveillance and utilization control program (SURS) that safeguards against unnecessary or inappropriate utilization of care and services and excess payments. Cases of suspected fraud, waste and abuse, which originate from various sources including SURS, are reviewed in DFWAIP for possible administrative action. When evidence presents of possible criminal activity, referral is made to the OIG, Division of Special Investigations (DSI) for further investigation. DSI will investigate and when appropriate make the necessary referrals to law enforcement, including the Medicaid Fraud and Abuse Control Unit.

DFWAIP also houses the Drug Enforcement and Professional Practices Branch (DEPPB), which administers the KASPER system, and enforces the Kentucky Controlled Substance Act and the Kentucky Food Drug and Cosmetics Act through the investigative arm of the Branch. Kentucky is currently the only state that houses its PMP and prescription drug abuse and diversion investigative agency in the same organization as the Medicaid fraud and abuse agency. This successful integration did not exist prior to the 2004 reorganization. Cases of suspected Medicaid fraud that also present evidence of illegal diversion or abuse of controlled substances, irrespective of payer source, are now referred to the DEPPB. These include cases under preliminary or full investigation by the DSI. When investigators with the DEPPB suspect fraud and abuse within Medicaid, a referral is made through the DFWAIP Director to the DSI.

The Division of Fraud, Waste and Abuse Identification and Prevention Mission and Vision statements are:

Mission Statement: "To plan, develop, and direct efforts to identify and prevent fraud, waste and abuse in the Medicaid program, and other public assistance programs administered by the Cabinet, and to aid in the prevention and enforcement of controlled substance abuse by specialized regulatory enforcement matters involving the dispensing of controlled substances in the Commonwealth."

Vision Statement: "To lead the OIG efforts to systematically identify and prevent fraud, waste and abuse by strong administrative enforcement within Medicaid and all public assistance programs administered by the Cabinet; to fulfill at the highest level of competence the specialized regulatory enforcement and compliance mandate involving the dispensing of controlled substances, and to merge these efforts wherever possible into one cohesive and effective effort.

The Division of Fraud, Waste and Abuse Identification and Prevention has identified the following Critical Success Factors as part of the Cabinet for Health and Family Services 3 Year Strategic Plan.

- Increased identification and prevention of fraud, waste and abuse by Medicaid providers through third party liability and other pre-payment and post-payment review activities.
- Increased identification and prevention of fraud, waste and abuse by Medicaid and public assistance recipients through policy edits, collections, sanctions and other administrative enforcement activities.
- Maximization of current eKASPER system, including future enhancements to the system, as a critical tool for prescription drug abuse prevention and enforcement.

DFWAIP Innovation

The DFWAIP has implemented several innovations that are increasing the efficiency of the program integrity function, and resulting in cost savings for the Medicaid program. Indicative of these innovations is the recognition of DFWAIP Benchmark Processes by the Centers for Medicare & Medicaid Services (CMS) within the U.S. Department of Health & Human Services. During the week of August 8, 2005 a team of Medicaid Fraud and Abuse Coordinators from CMS, conducted a review of Kentucky's program integrity procedures. The purpose of the review was to determine whether the program integrity policies and procedures of the Cabinet for Health and Family Services comply with federal statutory and regulatory requirements. During the review the CMS team identified Benchmark Processes implemented by OIG and DFWAIP. Following are the Benchmark Processes that were identified in the CMS Review Report.

1. The reorganization of the Cabinet resulted in moving the former Division of Program Integrity out from under the Department of Medicaid Services. The new Division of Fraud, Waste and Abuse Identification and Prevention reports directly to the CHFS Inspector General who reports directly to the Cabinet Secretary.

2. Organizationally housing the management responsibility for Kentucky's electronic prescription monitoring system (KASPER) in DFWAIP allows for improved fiscal integrity related to pharmaceutical behaviors in the Medicaid program.
3. DFWAIP's "correspondence campaign" alerts physicians to potentially abusive Medicaid client behaviors of which they may have previously been unaware. Doing so provides a sentinel effect on both physician and client behavior.
4. During provider enrollment, Kentucky also checks the General Service Administration's Excluded Parties List System (EPLS) before issuing an enrollment number. Although not specifically required to do so by federal regulation, Kentucky will not issue a provider number to a person or entity on the EPLS.

DFWAIP Staffing and Functions

Division staff have special expertise in investigating and consulting with law enforcement to prevent the diversion of prescription controlled substances through the enhanced KASPER program, an online database that tracks and monitors prescription drug dispensation of controlled substances. They also verify that medical services are appropriate and rendered as billed, that services are provided by qualified providers to eligible recipients, that payments for those services are correct, including payments made by the appropriate payer (coordination of benefits), and that all funds identified for collection are fully pursued.

The division targets Medicaid and other health care provider compliance and enforcement issues in addition to Medicaid and other welfare recipient compliance and enforcement. The division also focuses on the involvement of third parties in this process, such as insurance carriers and other government health care payers, and pharmaceutical manufacturers. The division serves as the immediate liaison to the Medicaid and welfare program agencies within the cabinet and serves as the primary referral source to special investigative and enforcement functions within the Office of the Inspector General.

Division staff members also perform specialized recovery and cost avoidance functions, including monitoring aged debts and accounts receivable within Medicaid, and all third party liability recovery and cost avoidance. The division has three branches: Medicaid Provider and Third Party Compliance, Programs Enforcement, and the Drug Enforcement and Professional Practices Branch which is responsible for the KASPER program.

An organization chart for the Division of Fraud, Waste and Abuse Identification and Prevention is shown in Appendix E.2.

5.3 Drug Enforcement and Professional Practices Branch

Within the Division of Fraud, Waste and Abuse Identification and Prevention, the Drug Enforcement and Professional Practices Branch (DEPPB) is responsible for administration and enforcement of the Kentucky Controlled Substances Act (KRS 218A), the Kentucky Food, Drug and Cosmetic Act (KRS 217), and for administration of the KASPER program. The Drug Enforcement and Professional Practices Branch mission statement is:

Mission Statement: "To protect citizens of the Commonwealth by diminishing the diversion of legal controlled substances and ensuring the high quality of patient care by administration of the KASPER program, investigating and enforcing infractions of KRS 218A, licensing wholesalers and distributors of controlled substances and serving as consultants to law enforcement agencies on drug related issues."

DEPPB Staffing

The DEPPB is currently staffed by six full time pharmacists, and three administrative personnel. Five of the branch's pharmacists are sworn law enforcement officers who enforce the provisions of KRS 218A (Controlled Substances Act) as well as KRS 217, (Food, Drug and Cosmetic Act). DEPPB investigators have the same authority as any other law enforcement agent regarding drug investigations. The investigative side is made up of a supervisor and three field investigators. With limited investigative resources investigations are prioritized with the main focus being on health care providers, including, but not limited to physicians, dentists, pharmacists, nurses and veterinarians. Appendix F. OIG Drug Enforcement Investigators contains an article reprinted from the Cabinet for Health and Family Services CHFS Focus Newsletter, describing the current DEPPB investigative staff. The Division of Fraud, Waste and Abuse Identification and Prevention - Organization Chart shown in Appendix E.2 includes the DEPPB organization.

DEPPB Functions

Investigators in the DEPPB work closely with the Kentucky State Police, Kentucky Bureau of Investigation, U.S. Drug Enforcement Administration and local law enforcement agencies, in addition to professional licensure boards such as the Kentucky Board of Medical Licensure, Kentucky Board of Dentistry, Kentucky Board of Nursing and Kentucky Board of Pharmacy. Most violations investigated by DEPPB investigators may be charged criminally and/or administratively.

Other duties administered by the DEPPB include:

- Licensing over 200 manufacturers/distributors.
- Handling over 300 phone calls per month regarding controlled substance issues.
- 240 ongoing drug investigations.
- Producing over 600 KASPER reports per day for qualified requestors. Weekday volumes are often over 1000 reports per day.
- Fulfilling requests for presentations relating to the branch's activities and for KASPER presentations and training.
- Serving in a consulting capacity for law enforcement agencies requiring assistance with controlled substance related issues and investigations.
- Conducting training classes for law enforcement organizations and meetings, including development of a training videotape for use by police organizations (other than the Kentucky State Police) for use in their continuing education programs.

Special Projects

Recent special projects undertaken by the DEPPB include:

- Completing the move from the Department of Public Health to the Office of the Inspector General.
- Restructuring the branch and appointing a Supervisor of Investigations.
- Developing databases to track:
  - Complaints/investigations.
  - Licenses.
  - Theft and losses of controlled substances.
- Reworking license application and update forms.
- Participating in the Lieutenant Governor's Drug summit.
- Participating in the Attorney General's Internet Pharmacy Task Force.
- Supervising development work on eKASPER.
- Processing license renewal notices for manufacturers and/or wholesalers distributing controlled substances in Kentucky

Notable Accomplishments

During 2004, DEPPB prosecuted either administratively or criminally:

- 41 Physicians
- 5 Pharmacists
- 1 Physician Assistant
- 2 Advanced Registered Nurse Practitioners
- 3 Nurses

DEPPB staff conducted "doctor shopper" training sessions for Kentucky State Police and Operation UNITE (Unlawful Narcotics Investigations, Treatment and Education) personnel, and participated in investigations conducted by those organizations.

DEPPB conducts ongoing education and training which are discussed in detail in section 9 KASPER Education and Training.

DEPPB staff played a key role in a major raid on illegal Internet pharmacies in Tampa, Florida that were shipping controlled substances into Kentucky. Kentucky has been designated to receive a large share of confiscated funds as a result of the DEPPB role in this investigation and seizure.

During 2005, the DEPPB renegotiated and extended a contract to provide investigative support for the Kentucky Board of Medical Licensure.

DEPPB Process Improvement Plans

DEPPB is currently working on several activities that will help improve the operations of the branch and the effectiveness of the KASPER program, including a major DEPPB Business Process Improvement Project. Key activities include:

- Continuing to develop and implement KASPER training programs for health care and law professionals, law enforcement officials, attorneys and judges, and public organizations.
- Branch personnel will work with the Cabinet for Health and Family Services, Office of Information Technology to direct further enhancements to the eKASPER system.
- Working with PMP officials and programs in other states to plan for sharing of PMP data among states, especially Kentucky border states.
- Promulgating new regulations to conform controlled substance regulations to federal statutes by reference, and promulgating new regulations in 902 KAR 55:110 to conform to changes made to KRS 218A.202.
- Working closely with the Kentucky Board of Pharmacy to enforce compliance of pharmacy controlled substance data transmissions to the KASPER database.

DEPPB Business Process Improvement Project

One of the major activities being undertaken to help improve the KASPER program, is a project to review and improve the DEPPB business processes. This project was identified as a planned activity under the 2005 Harold Rogers Grant program. The key objective of this project is to analyze and streamline the business processes of the DEPPB in order to allow more branch resources to focus on investigative tasks. The DEPPB has engaged experienced organizational consultants from the Kentucky Personnel Cabinet's Office of Employee and Organizational Development (OEOD). The organizational consultants will work closely with the DEPPB personnel to accomplish the following activities:

- identify the process improvement goals and an initial set of potential improvement areas,
- assess and document the current business processes, including development of as-is process maps,

- analyze the as-is processes to identify improvements that will support more effective and efficient operations, improved customer response time and satisfaction, and improved utilization of staff to support investigative activities,
- develop a plan for implementation of the business process improvements, and
- develop an evaluation plan to track performance against the established goals and to facilitate continuous business process improvements.

The DEPPB business process improvement project kickoff was conducted in November 2005 and the project is planned to be completed by the first quarter of 2006.

6 Legislative Control and Review of KASPER

6.1 Kentucky Revised Statute 218A.202

218A.202 Electronic system for monitoring controlled substances -- Penalty for illegal use of system -- Pilot project -- Continuing education programs.

(1) The Cabinet for Health Services shall establish an electronic system for monitoring Schedules II, III, IV, and V controlled substances that are dispensed within the Commonwealth by a practitioner or pharmacist or dispensed to an address within the Commonwealth by a pharmacy that has obtained a license, permit, or other authorization to operate from the Kentucky Board of Pharmacy.
(2) A practitioner or a pharmacist shall not have to pay a fee or tax specifically dedicated to the operation of the system.
(3) Every dispenser within the Commonwealth or any other dispenser who has obtained a license, permit, or other authorization to operate from the Kentucky Board of Pharmacy shall report to the Cabinet for Health Services the data required by this section in a timely manner as prescribed by the cabinet except that reporting shall not be required for:
(a) A drug administered directly to a patient; or
(b) A drug dispensed by a practitioner at a facility licensed by the cabinet provided that the quantity dispensed is limited to an amount adequate to treat the patient for a maximum of forty-eight (48) hours.
(4) Data for each controlled substance that is dispensed shall include but not be limited to the following:
(a) Patient identifier;
(b) Drug dispensed;
(c) Date of dispensing;
(d) Quantity dispensed;
(e) Prescriber; and
(f) Dispenser.
(5) The data shall be provided in the electronic format specified by the Cabinet for Health Services unless a waiver has been granted by the cabinet to an individual dispenser. The cabinet shall establish acceptable error tolerance rates for data. Dispensers shall ensure that reports fall within these tolerances. Incomplete or inaccurate data shall be corrected upon notification by the cabinet if the dispenser exceeds these error tolerance rates.
(6) The Cabinet for Health Services shall be authorized to provide data to:
(a) A designated representative of a board responsible for the licensure, regulation, or discipline of practitioners, pharmacists, or other person who is authorized to prescribe, administer, or dispense controlled substances and who is involved in a bona fide specific investigation involving a designated person;
(b) A Kentucky peace officer certified pursuant to KRS 15.380 to 15.404, a certified or full-time peace officer of another state, or a federal peace officer whose duty is to enforce the laws of this Commonwealth, of another state, or of the United States relating to drugs and who is engaged in a bona fide specific investigation involving a designated person;
(c) A state-operated Medicaid program;
(d) A properly convened grand jury pursuant to a subpoena properly issued for the records;
(e) A practitioner or pharmacist who requests information and certifies that the requested information is for the purpose of providing medical or pharmaceutical treatment to a bona fide current patient;
(f) In addition to the purposes authorized under paragraph (a) of this subsection, the Kentucky Board of Medical Licensure, for any physician who is:
1. Associated in a partnership or other business entity with a physician who is already under investigation by the Board of Medical Licensure for improper prescribing practices;
2. In a designated geographic area for which a trend report indicates a substantial likelihood that inappropriate prescribing may be occurring; or

3. In a designated geographic area for which a report on another physician in that area indicates a substantial likelihood that inappropriate prescribing may be occurring in that area; or
(g) A judge or a probation or parole officer administering a diversion or probation program of a criminal defendant arising out of a violation of this chapter or of a criminal defendant who is documented by the court as a substance abuser who is eligible to participate in a court-ordered drug diversion or probation program.
(7) The Department for Medicaid Services may use any data or reports from the system for the purpose of identifying Medicaid recipients whose usage of controlled substances may be appropriately managed by a single outpatient pharmacy or primary care physician.
(8) A person who receives data or any report of the system from the cabinet shall not provide it to any other person or entity except by order of a court of competent jurisdiction, except that:
(a) A peace officer specified in subsection (6)(b) of this section who is authorized to receive data or a report may share that information with other peace officers specified in subsection (6)(b) of this section authorized to receive data or a report if the peace officers specified in subsection (6)(b) of this section are working on a bona fide specific investigation involving a designated person. Both the person providing and the person receiving the data or report under this paragraph shall document in writing each person to whom the data or report has been given or received and the day, month, and year that the data or report has been given or received. This document shall be maintained in a file by each law enforcement agency engaged in the investigation; and
(b) A representative of the Department for Medicaid Services may share data or reports regarding overutilization by Medicaid recipients with a board designated in paragraph (a) of subsection (6) of this section, or with a law enforcement officer designated in paragraph (b) of subsection (6) of this section; and
(c) The Department for Medicaid Services may submit the data as evidence in an administrative hearing held in accordance with KRS Chapter 13B.
(9) The Cabinet for Health Services, all peace officers specified in subsection (6)(b) of this section, all officers of the court, and all regulatory agencies and officers, in using the data for investigative or prosecution purposes, shall consider the nature of the prescriber's and dispenser's practice and the condition for which the patient is being treated.
(10) The data and any report obtained therefrom shall not be a public record, except that the Department for Medicaid Services may submit the data as evidence in an administrative hearing held in accordance with KRS Chapter 13B.
(11) Knowing failure by a dispenser to transmit data to the cabinet as required by subsection (3), (4), or (5) of this section shall be a Class A misdemeanor.
(12) Knowing disclosure of transmitted data to a person not authorized by subsection (6) to subsection (8) of this section or authorized by KRS 315.121, or obtaining information under this section not relating to a bona fide specific investigation, shall be a Class D felony.
(13) The Governor's Office for Technology, in consultation with the Cabinet for Health Services, shall submit an application to the United States Department of Justice for a drug diversion grant to fund a pilot project to study a real-time electronic monitoring system for Schedules II, III, IV, and V controlled substances. The pilot project shall:
(a) Be conducted in two (2) rural counties that have an interactive real-time electronic information system in place for monitoring patient utilization of health and social services through a federally funded community access program; and
(b) Study the use of an interactive system that includes a relational data base with query capability.
(14) Provisions in this section that relate to data collection, disclosure, access, and penalties shall apply to the pilot project authorized under subsection (13) of this section.
(15) The Cabinet for Health Services may limit the length of time that data remain in the electronic system. Any data removed from the system shall be archived and subject to retrieval within a reasonable time after a request from a person authorized to review data under this section.
(16) (a) The Cabinet for Health Services shall work with each board responsible for the licensure, regulation, or discipline of practitioners, pharmacists, or other persons who are authorized to prescribe, administer, or

dispense controlled substances for the development of a continuing education program about the purposes and uses of the electronic system for monitoring established in this section.
(b) The cabinet shall work with the Kentucky Bar Association for the development of a continuing education program for attorneys about the purposes and uses of the electronic system for monitoring established in this section.
(c) The cabinet shall work with the Justice Cabinet for the development of a continuing education program for law enforcement officers about the purposes and users of the electronic system for monitoring established in this section.

Effective: July 13, 2004

History: Amended 2004 Ky. Acts ch. 68, sec. 1, effective July 13, 2004; and ch. 107, sec. 1, effective July 13, 2004. -- Amended 2002 Ky. Acts ch. 295, sec. 1, effective April 9, 2002. -- Created 1998 Ky. Acts ch. 301, sec. 13, effective July 15, 1998.

Legislative Research Commission Note (7/13/2004). This section was amended by 2004 Ky. Acts. chs. 68 and 107. Where these Acts are not in conflict, they have been codified together. Where a conflict exists, Acts. ch. 107, which was last enacted by the General Assembly, prevails under KRS 446.250.

6.2 Kentucky Revised Statute 218A.240

218A.240 Controlled substances -- Duties and authority of state and local officers, Cabinet for Health Services, and Kentucky Board of Pharmacy -- Civil proceedings -- Identification of trends.

(1) All police officers and deputy sheriffs directly employed full-time by state, county, city, or urban-county governments, the State Police, the Cabinet for Health Services, their officers and agents, and of all city, county, and Commonwealth's attorneys, and the Attorney General, within their respective jurisdictions, shall enforce all provisions of this chapter and cooperate with all agencies charged with the enforcement of the laws of the United States, of this state, and of all other states relating to controlled substances.
(2) For the purpose of enforcing the provisions of this chapter, the designated agents of the Cabinet for Health Services shall have the full power and authority of peace officers in this state, including the power of arrest and the authority to bear arms, and shall have the power and authority to administer oaths, to enter upon premises at all times for the purpose of making inspections, to seize evidence, to interrogate all persons, to require the production of prescriptions, of books, papers, documents or other evidence, to employ special investigators, and to expend funds for the purpose of obtaining evidence and to use data obtained under KRS 218A.202(7) in any administrative proceeding before the cabinet.
(3) The Kentucky Board of Pharmacy, its agents and inspectors, shall have the same powers of inspection and enforcement as the Cabinet for Health Services.
(4) Designated agents of the Cabinet for Health Services and the Kentucky Board of Pharmacy are empowered to remove from the files of a pharmacy or the custodian of records for that pharmacy any controlled substance prescription or other controlled substance record upon tendering a receipt. The receipt shall be sufficiently detailed to accurately identify the record. A receipt for the record shall be a defense to a charge of failure to maintain the record.
(5) Notwithstanding the existence or pursuit of any other remedy, civil or criminal, any law enforcement authority may maintain, in its own name, an action to restrain or enjoin any violation of this chapter, or to forfeit any property subject to forfeiture under KRS 218A.410, irrespective of whether the owner of the property has been charged with or convicted of any offense under this chapter.
(a) Any civil action against any person brought pursuant to this section may be instituted in the Circuit Court in any county in which the person resides, in which any property owned by the person and subject to forfeiture is found, or in which the person has violated any provision of this chapter.
(b) A final judgment rendered in favor of the Commonwealth in any criminal proceeding brought under this chapter shall estop the defendant from denying the essential allegations of the criminal offense in any subsequent civil proceeding brought pursuant to this section.
(c) The prevailing party in any civil proceeding brought pursuant to this section shall recover his costs, including a reasonable attorney's fee.
(d) Distribution of funds under this section shall be made in the same manner as in KRS 218A.435, except that if the Commonwealth's attorney has not initiated the forfeiture action under this section, his percentage of the funds shall go to the agency initiating the forfeiture action.
(6) The Cabinet for Health Services shall make or cause to be made examinations of samples secured under the provisions of this chapter to determine whether any provision has been violated.
(7) (a) The Cabinet for Health Services shall use the data compiled in the electronic system created in KRS 218A.202 for investigations, research, statistical analysis, and educational purposes, and shall proactively identify trends in controlled substance usage and other potential problem areas. Only cabinet personnel who have undergone training for the electronic system and who have been approved to use the system shall be authorized access to the data and reports under this subsection. The cabinet shall notify a board responsible for the licensure, regulation, or discipline of each practitioner, pharmacist, or other

person who is authorized to prescribe, administer, or dispense controlled substances, if a report or analysis conducted under this subsection indicates that further investigation about inappropriate or unlawful prescribing or dispensing may be necessary by the board.
(b) The cabinet shall develop criteria, in collaboration with the Board of Medical Licensure and the Board of Pharmacy, to be used to generate trend reports from the data obtained by the system. Meetings at which the criteria are developed shall be meetings, as defined in KRS 61.805, that comply with the open meetings laws, KRS 61.805 to 61.850.
(c) The cabinet shall, on a quarterly basis, publish trend reports from the data obtained by the system.
(d) Peace officers authorized to receive data under KRS 218A.202 may request trend reports not specifically published pursuant to paragraph (c) of this subsection. A report under this paragraph may be based upon the criteria developed under paragraph (b) of this subsection or upon any of the data collected pursuant to KRS 218A.202(4), except that the report shall not identify an individual prescriber, dispenser, or patient.
(e) No trend report generated under this subsection shall identify an individual prescriber, dispenser, or patient.

Effective: July 13, 2004

History: Amended 2004 Ky. Acts ch. 68, sec. 2, effective July 13, 2004; and ch. 107, sec. 2, effective July 13, 2004. -- Amended 1998 Ky. Acts ch. 301, sec. 26, effective July 15, 1998; and ch. 426, sec. 487, effective July 15, 1988. -- Amended 1992 Ky. Acts ch. 441, sec. 28, effective July 14, 2992. -- Amended 1974 Ky. Acts ch. 74, Art. VI, sec. 107(3). -- Created 1972 Ky. Acts ch. 226, sec. 26.

Legislative Research Commission Note (7/13/2004). This section was amended by 2004 Ky. Acts. chs. 68 and 107, which do not appear to be in conflict and have been codified together.

6.3 Title 902 Kentucky Administrative Regulation 55:110

902 KAR 55:110. Monitoring system for prescription controlled substances.

RELATES TO: KRS 218A.202
STATUTORY AUTHORITY: KRS 194A.030, 194A.050, 211.090, 218A.202, 218A.250
NECESSITY, FUNCTION, AND CONFORMITY: KRS 218A.202 directs the Cabinet for Health Services to establish an electronic system for monitoring Schedule II, III, IV, and V controlled substances that are dispensed in the Commonwealth or dispensed to an address within the Commonwealth. The purpose of the system is to improve access to controlled substances for legitimate medical needs by allowing a practitioner or a pharmacist to obtain a patient's pharmaceutical history related to controlled substances. Also the system will enable regulatory or law enforcement agencies to address violations of KRS Chapter 218A. The purpose of this administrative regulation is to establish the criteria for reporting prescription data, for providing reports to authorized persons, and for a waiver for a dispenser who does not have an automated recordkeeping system.
Section 1. Definitions.
(1) "Patient identifier" means a patient's:
(a) Full name;
(b) Address, including zip code;
(c) Date of birth; and
(d) Social Security number or an alternative identification number established pursuant to Section 5 of this administrative regulation.
(2) "Pharmacy Universal Claim Form" means a form that:
(a) Is in the format of the "Pharmacy Universal Claim Form" incorporated by reference in Section 6 of this administrative regulation; and
(b) Contains the information specified by Section 2(2) of this administrative regulation.
(3) "Report" means a compilation of data concerning a patient, a dispenser, a practitioner, or a controlled substance.
Section 2. Data Reporting.
(1) A dispenser shall report all controlled substances dispensed after December 31, 1998.
(2) A dispenser of a Schedule II, III, IV, or V controlled substance shall transmit or provide the following data to the cabinet or the cabinet's agent:
(a) Patient identifier;
(b) National drug code of the drug dispensed;
(c) Metric quantity of drug dispensed;
(d) Date of dispensing;
(e) Estimated days supply dispensed;
(f) Drug Enforcement Administration registration number of the prescriber;
(g) Serial number assigned by the dispenser; and
(h) The Drug Enforcement Administration registration number of the dispenser.
(3)(a) The data shall be transmitted within sixteen (16) days of the date of dispensing unless the cabinet grants an extension.
(b) An extension may be granted if a dispenser suffers a mechanical or electronic failure, or cannot meet the deadline established by paragraph (a) of this subsection for other reasons beyond his control. A dispenser shall apply in writing for an extension. An application for an extension shall state the reason why an extension is required, and the period of time for which the extension is required.
(c) An extension shall be granted to all dispensers if the cabinet or its agent is unable to receive electronic reports.
(4) Except as provided in subsection (7) of this section, the data shall be transmitted by:
(a) An electronic device compatible with the receiving device of the cabinet or the cabinet's agent;
(b) Double sided, high density micro floppy disk; or

(c) One-half (1/2) inch nine (9) track 1600 or 6250 BPI magnetic tape.
(5) The data shall be transmitted in the format established by the "ASAP Telecommunications Format for Controlled Substances".
(6) The cabinet shall provide a toll-free telephone number for transmitting electronic reports by modem.
(7)(a) A dispenser, who does not have an automated recordkeeping system capable of producing an electronic report in the format established by "ASAP Telecommunications Format for Controlled Substances", may request a waiver from electronic reporting. The request shall be made to the cabinet in writing.
(b) A dispenser shall be granted a waiver, if he agrees in writing to report the data by submitting a completed "Pharmacy Universal Claim Form".
Section 3. Compliance.
(1) A dispenser shall be deemed to be the person who is registered with the U.S. Drug Enforcement Administration.
(2) A dispenser may presume that the patient identification information provided by the patient or the patient’s agent is correct.
Section 4. Request for Report.
(1) A written request shall be filed with the cabinet prior to the release of a report.
(2) A request for a report shall be made on Request for KASPER Report, Form DCB-15 except for a subpoena issued by a grand jury.
Section 5. Alternative Patient Identification Number.
(1) If a patient does not have a Social Security number, or refuses to provide a Social Security number, the patient’s driver’s license number shall be used.
(2) If a patient does not have a Social Security number or a driver’s license number, the number 000-00-0000 shall be used.
(3) The number "999-99-9999" shall be used if a patient or a patient's agent refuses to provide a Social Security number or driver's license number.
(4) If a patient is a child who does not have a Social Security number, the Social Security number, driver's license number, or the number "000-00-0000", as applicable, of the parent or guardian shall be used.
(5) If a patient is an animal, the owner’s Social Security number, or driver's license number, or the number "000-00-0000", as applicable shall be used.
(6) If a patient’s Social Security number is not available, the Social Security number, or driver's license number, or the number "000-00-0000", as applicable, of the person obtaining the controlled substance on behalf of the patient shall be used.
(7) If the patient or the patient’s agent refuses to provide a Social Security number or driver’s license, the number 999-99-9999 shall be used.
Section 6. Incorporation by Reference.
(1) The following material is incorporated by reference:
(a) "ASAP Telecommunications Format for Controlled Substances", American Society for Automation in Pharmacy, May, 1995;
(b) "Pharmacy Universal Claim Form"; and
(c) "Request for KASPER Report, DCB-15, 9-98".
(2) This material may be inspected, copied, or obtained at the Department for Public Health, 275 E. Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m. (25 Ky.R. 966; Am. 1367; eff. 12-16-98.)

6.4 Proposed Regulation Changes – 902 KAR 55:110

The Cabinet for Health and Family Services, Office of the Inspector General is promulgating changes to the KASPER regulations contained in 902 KAR 55:110, during the 2006 legislative session. The changes are primarily intended to reduce the time delay in making prescription data available in the KASPER database, to provide for data transmission in formats established by the Drug Enforcement and Professional Practices Branch, and to improve the accuracy of patient identification information in KASPER. A summary of the key proposed changes to 902 KAR 55:110 that will impact KASPER follow.

Prescription Reporting Period

Require dispensers of Schedule II, III, IV and V controlled substances to transmit the data within eight (8) days, versus the current regulation which requires transmission within sixteen (16) days.

Current:

> Section 2. Data Reporting.
> (3)(a) The data shall be transmitted within sixteen (16) days of the date of dispensing unless the cabinet grants an extension.

Proposed:

> Section 2. Data Reporting.
> (3) The data shall be transmitted within eight (8) days of the date of dispensing unless the cabinet grants an extension.

Data Reporting Format

Provide for transmission of data using a format established by the Drug Enforcement and Professional Practices Branch. This change will allow DEPPB to move dispensers to more current transmission standards without having to seek future regulation changes.

Current:

> Section 2. Data Reporting.
> (5) The data shall be transmitted in the format established by the "ASAP Telecommunications Format for Controlled Substances".

Proposed:

> Section 2. Data Reporting.
> (7) The data shall be transmitted in the format established by the "ASAP Telecommunications Format for Controlled Substances", American Society for Automation in Pharmacy, May 1995, or other format as established by the branch.

Report Requests

Clarify that KASPER report requests may also be made via the KASPER Web site, and expand the exception to include a KASPER report request from a court order issued by a court of competent jurisdiction.

Current:

> Section 4. Request for Report.
> (1) A written request shall be filed with the cabinet prior to the release of a report.

(2) A request for a report shall be made on Request for KASPER Report, Form DCB-15 except for a subpoena issued by a grand jury.

Proposed:

Section 4. Request for Report.
(1) A written or electronic request shall be filed with the cabinet prior to the release of a report. (2) A request for a report shall be made on "Request for KASPER Report", Form DCB-15 or the website designated by the cabinet, except for a subpoena issued by a grand jury or by an appropriate court order by a court of competent jurisdiction.

Positive Identification

One of the greatest challenges in operating a PMP is to obtain the most accurate data possible related to the identity of a patient. There is no current single mandatory form of identification required when a patient picks up a controlled substance prescription drug, and under current statutes, a patient may refuse to provide positive identification. The KASPER system has been designed with a complex data matching algorithm for analyzing available identification data such as name, address, social security number, date of birth, etc. to increase the accuracy of matching controlled substance prescription data with the proper patient. To further improve the accuracy of KASPER patient reports, the following regulation change is being proposed to tighten the requirement for the patient or a person obtaining a controlled substance on behalf of the patient, to disclose to the dispenser the patient's Social Security number or driver's license number for purposes of the dispenser's mandatory reporting to KASPER. This regulation change would in effect eliminate the patient's option to simply refuse to provide positive identification, so that KASPER will be able to capture more accurate identification data if available.

Current:

Section 5. Alternative Patient Identification Number.
(1) If a patient does not have a Social Security number, or refuses to provide a Social Security number, the patient's driver's license number shall be used.
(2) If a patient does not have a Social Security number or a driver's license number, the number 000-00-0000 shall be used.
(3) The number "999-99-9999" shall be used if a patient or a patient's agent refuses to provide a Social Security number or driver's license number.
(4) If a patient is a child who does not have a Social Security number, the Social Security number, driver's license number, or the number "000-00-0000", as applicable, of the parent or guardian shall be used.
(5) If a patient is an animal, the owner's Social Security number, or driver's license number, or the number "000-00-0000", as applicable shall be used.
(6) If a patient's Social Security number is not available, the Social Security number, or driver's license number, or the number "000-00-0000", as applicable, of the person obtaining the controlled substance on behalf of the patient shall be used.
(7) If the patient or the patient's agent refuses to provide a Social Security number or driver's license, the number 999-99-9999 shall be used.

Proposed:

Section 5. Patient Identification Number.
(1) A patient or the person obtaining the controlled substance on behalf of the patient shall disclose to the dispenser the patient's Social Security Number for purposes of the dispenser's mandatory reporting to KASPER.
(2) If a patient does not have a Social Security number, the patient's driver's license number shall be disclosed.

(3) If a patient has not been assigned a Social Security number or a driver's license number, the number 000-00-0000 shall be used.
(4) If a patient is a child who does not have a Social Security number or a driver’s license number, the Social Security number, driver's license number, or the number "000-00-0000", as applicable, of the parent or guardian shall be used.
(5) If a patient is an animal, the owner’s Social Security number or driver's license number or the number "000-00-0000", as applicable, shall be used.

6.5 Responses to Legislative and Task Force Recommendations

The Legislative Research Commission (LRC) was established in 1948 as a fact-finding and service body for the Kentucky Legislature. The LRC is a 16 member panel that consists of the Democratic and Republican leaders from the House of Representatives and the Senate. The LRC is administered by a full-time director who presides over a highly-trained staff of researchers, fiscal analysts, attorneys, computer operators, librarians, secretaries and others who provide expert services to the legislators. Services provided by the LRC include: committee staffing, bill drafting, oversight of the state budget and educational reform, production of educational materials, maintenance of a reference library and Internet site, and the preparation and printing of research reports, informational bulletins and a legislative newspaper.

In August 2005, the LRC conducted a review of the eKASPER system and the Hal Rogers Grant activities being performed in support of the KASPER program. Following are the LRC discussion point questions, and responses from the Office of the Inspector General, which were produced as part of the LRC review, including the status of recommendations made by the Prescription Drug Abuse Task Force established under House Bill 303 in 2003.

Discussion Points

Question 1. What is the status of the recommendations made in Prescription Drug Abuse Task Force Final Report (House Bill 303)? We know that some recommendations have been incorporated in statute. What specifically has been done to implement each of the following recommendations?

Answer: Refer to the Action Taken / Status field in the following table of recommendations.

Recommendation	Action Taken / Status
a. Submission of data by dispensers: data should be submitted at least weekly and CHS should develop more efficient and effective methods for the transmission of point-of-sale data.	We are in the process of changing the wording in 902 KAR 55:110 requiring data submission every seven days.
b. Dispensers should be required to submit data accurately.	KRS 218A.202 (5) was modified to read "The cabinet shall establish acceptable error tolerance rates for data. Dispensers shall ensure that reports fall within these tolerances. Incomplete or inaccurate data shall be corrected upon notification by the cabinet if the dispenser exceeds these error tolerance rates."
c. Unique patient identifier requirement should be strengthened.	In the modifications being developed for 902 KAR 55:110 we hope to limit the use of "standard" identification numbers and strongly recommend the use of social security numbers for each person receiving a controlled substance prescription.
d. Cabinet for Health Services should work with dispensing community to explore possibility of adding data fields, particularly method of payment.	Discussions have been held, through the focus groups established as part of the Hal Rogers Grant program regarding adding payer information to the database. One problem is that the data set (ASAP 95) established by the KASPER legislation does not contain that information. A regulation change would be required to require a different data set and each dispenser in the state would be required to have their

	dispensing software modified.
e. The Cabinet for Health Services should be given the authority to limit the length of time patient information remains active in the KASPER database	KRS 218A.202 (15) was added and says "The Cabinet for Health and Family Services may limit the length of time that data remain in the electronic system. Any data removed from the system shall be archived and subject to retrieval within a reasonable time after a request from a person authorized to review data under this section."
f. The lag-time between the request and the receipt of a KASPER report should be reduced	In March of 2005 the eKASPER (Web-based) system was introduced allowing "real time" (within 15 minutes) access to data. Eighty percent of the Web requests for KASPER reports are ready to be printed by the requestor in less than 15 minutes.
g. CHS should enter into agreements with other states to share information.	Informal contacts have been made, but neighboring states either do not have active programs or their programs are so new they are not prepared to work on information sharing. Opportunities in this area will be furthered through the National Alliance for Model State Drug Laws and National Association of State Controlled Substance Authorities. We will be represented at both meetings.
h. Law enforcement agencies and officers should be allowed to share KASPER reports and information when working on joint or related investigations.	KRS 218A.202 (8)(a) was added and reads: "A peace officer specified in subsection (6)(b) of this section who is authorized to receive data or a report may share that information with other peace officers specified in subsection (6)(b) of this section authorized to receive data or a report if the peace officer specified in subsection (6)(b) of this section are working on a bona fide specific investigation involving a designated person. Both the person providing and the person receiving this data or report under this paragraph shall document in writing each person to whom the data or report has been given or received and the day, month, and year that the data or report has been given or received. This document shall be maintained in a file by each law enforcement agency engaged in the investigation; and"
i. Board of Medical Licensure should be authorized to receive KASPER reports in certain instances.	KRS 218A.202 (6)(f) was added and reads: "In addition to the purposes authorized under paragraph (a) of this subsection, the Kentucky Board of Medical Licensure, for any physician who is: 1. Associated in a partnership or other business entity with a physician who is already under investigation by the Board of Medical Licensure for improper prescribing practices; 2. In a designated geographic area for which a trend report indicates a substantial likelihood that inappropriate prescribing may be occurring; or In a designated geographic area for which a report on another physician in that area indicates a substantial likelihood that inappropriate prescribing may be occurring in that area"

j. The Medicaid program should be given the authority to share KASPER reports and other information regarding overutilization of scheduled drugs with regulatory boards and law enforcement officials.	KRS 218A (8) (b) was added and reads: "A representative of the Department for Medicaid Services may share data or reports regarding over utilization by Medicaid recipients with a board designated in paragraph (a) of subsection (6) of this section" and "The department for Medicaid Services may submit the data as evidence in an administrative hearing held in accordance with KRS Chapter 13B."
k. Judges, probation officers, and parole officers of drug courts should be allowed to request KASPER reports.	KRS 218A (6)(g) was added and reads: "A judge or a probation or parole officer administering a diversion or probation program of a criminal defendant arising out of a violation of this chapter or of a criminal defendant who is documented by the court as a substance abuser who is eligible to participate in a court-ordered drug diversion or probation program"
l. CHS should be required to use KASPER system data for educational, research, and statistical purposes to proactively identify trends and potential problem areas.	KRS 218A.240 (7) defines the requirement for the Cabinet for Health and Family Services to use the data for research, statistical analysis and educational purposes. The Cabinet utilized the Kentucky Injury Prevention and Research Center (KIPRC) to analyze KASPER data from 2000 – 2002 and establish a data baseline for further analysis. The Cabinet is currently working with the Board of Medical Licensure, the Board of Pharmacy and the Board of Dentistry to identify KASPER data trend reporting requirements and a quarterly reporting process that will allow the boards to identify trends and potential problem areas that they may need to address.
m. The Board of Pharmacy, Board of Medical Licensure, the Kentucky Bar Association, and the Justice Cabinet should work with CHS to develop continuing education programs regarding the purposes and appropriate use of the KASPER system	The Hal Rogers Grant working groups included members from the Professional Licensure Boards and Office of Drug Control Policy (Justice). Activities to address the requirement for continuing education include: 1. Development of brochures explaining KASPER and its role in fighting prescription drug abuse. There are three versions of the brochure addressing practitioners, law enforcement, and the general public. 2. A KASPER exhibit has been developed for use at trade shows and meetings. The exhibit allows us to provide information and answer questions about KASPER, and to promote the use of KASPER by authorized persons. 3. KASPER training presentations have been developed for training physicians, pharmacists and law enforcement on using the system. 4. A training presentation has been created and reviewed by an education committee from the working groups. This training is designed for practitioners and covers

	professional intervention as well as KASPER usage. We are pursuing making this training available on the Web, and providing Continuing Education Credit for successful completion of the training. 5. On an ongoing basis we are seeking opportunities to publish articles about KASPER in professional publications, trade journals, etc. and to present KASPER to practitioners, law enforcement, the legal community, and the general public, through appropriate venues (such as training at the Kentucky State Police Academy and KASPER exhibits at the 2005 Kentucky Bar Association Meeting and the Kentucky State Fair, etc.). The Hal Rogers Grant Phase I Findings and Recommendations Report identifies the sessions completed and scheduled as of June 30, 2005.
n. CHS should convene a multi-disciplinary group to assess the effectiveness of the KASPER system.	Under the 2004 Hal Rogers Grant, two interdisciplinary focus groups comprised of law enforcement and health care professionals were assembled. The focus groups were further broken down into working groups that met to review KASPER and issues related to pharmaceutical drug abuse and diversion. The working group recommendations are documented in the Working Groups Findings Summary dated July 13, 2005. During Phases II and III of the grant, efforts are underway to implement as many of the recommendations as feasible. In addition, a survey of KASPER system users was completed in 2005 with results summarized in the 2004 Grant Phase I Findings and Recommendations Report. The survey results were generally positive, and will provide us a baseline to track satisfaction with the system as we roll out eKASPER training and increase usage of the system.

Question 2. What is the status of the quarterly reports that were to be published by the Cabinet? Are those reports being produced? What information do they contain? May we obtain a generic version of a sample report?

Answer. A trend reporting working group organized under the 2004 Hal Rogers's Grant program, included Kentucky Board of Medical Licensure personnel and personnel of CHFS. The working group made general recommendations regarding KASPER data trend reporting. Using a state epidemiologist, KASPER and Hal Rogers Grant staff members are presently preparing prototype trend analysis reports to present to a second meeting of the trend reporting working group. When the trend analysis reports and process are approved the reports will be published quarterly.

Question 3. How has eKASPER performed since implementation? Specifically:

a. Volume of eKASPER.

Answer. When eKASPER began the KASPER staff was averaging around 600 reports per day. Six months after introducing eKASPER we are averaging over 700 reports per day.

b. Average time to complete request as compared to pre-eKASPER.

Answer. Prior to eKASPER it took from four hours to two weeks to receive a KASPER report after a request was sent. Today eighty percent of the Web requests are returned in less than 15 minutes.

c. Percent of requests that are fully automated.

Answer. Eighty percent.

d. Number of requests processed in off-business hours.

Answer. Ten requests.[4]

Question 4. What has been the feedback from practitioners concerning eKASPER?

Answer. The vast majority of comments received have been very positive. We've had a few complaints about our ID management requirements. Every new user of the Web-based system must supply their personal social security number and street address. Follow up KASPER Satisfaction Surveys will provide more detail regarding practitioners' satisfaction with eKASPER.

Question 5. What proportion of physicians are actively using KASPER? Have there been efforts to increase usage and, if so, how?

Answer. Most recent statistics show 3,067 reports run through the Web and 1,849 reports run by internal staff. We presently have 1,299 Web users of the KASPER system, including 1,104 from the medical field and 195 from law enforcement. The KASPER staff has made phone calls to higher volume users to encourage their change over to the Web-based system and staff has actually gone to the user's site to assist in establishing their Web accounts. Our educational initiatives are focused on increasing awareness of KASPER and eKASPER among practitioners, and to promoting usage of the system by additional practitioners.

Question 6. Concerning the Hal Rogers federal grants:

a. What were the objectives of the $350,000 grant received in 2004? How were these objectives met and what have been the outcomes?

Answer. Following are the five objectives for Phase I of the 2004 grant and a brief summary of the status. More detail can be found in the Phase I Findings and Recommendations Report.

1. Charter Focus Groups.
    - The Law Enforcement and Health Care focus groups were chartered and met twice to discuss issues related to pharmaceutical drug abuse and diversion. Six working groups were formed from members of the focus groups, to make specific recommendations to address issues related to prescription drug abuse and diversion. The recommendations are detailed in the Working Group

[4] At the time of the LRC review, ten was the average number of requests processed during off-business hours. As the Web-based eKASPER system has become more widely used this figure has increased to an average of approximately eighty requests per day processed during off-business hours.

Findings Summary dated July 13, 2005. Several recommendations have now been implemented and some are to be implemented as part of Phases II and III of the 2004 grant. Other recommendations were deemed to be outside the scope or control of the Cabinet for Health and Family Services, but the recommendations will be supported by the Cabinet.

2. Generate a KASPER Satisfaction Survey.
    - The KASPER Satisfaction Survey was completed and initial results compiled. A brief summary of the survey results is included in the Phase I Findings and Recommendations Report. The full report of survey results is available and was submitted along with the Phase I Report to the Dept. of Justice.
3. Gather Baseline Datasets.
    - The Cabinet contracted with the Kentucky Injury Prevention and Research Center (KIPRC) to analyze KASPER data, along with fatality data from the National Center for Health Statistics, and Kentucky COMPdata (hospital discharge data). The KIPRC analysis provides baseline data regarding demographic and geographic trends in prescriptions reported to KASPER, leading causes of death and injury among Kentucky residents, and associations between volumes of prescriptions filled and incidence of injury. The study results are summarized in the Phase I Report, and the full study report was submitted to the Department of Justice along with the report.
4. Create Education Intervention
    - The education intervention was completed in draft form and is being reviewed by an Education Committee comprised of selected members of the focus groups. This education intervention will be completed and made available to health care practitioners during Phases II and II. The intent is to develop this into Web-based training and to award Continuing Education credit for successful completion.
5. Identified Stratified Sample Population.
    - The population for KASPER usage has been identified and specific education and training approaches identified. For ongoing surveys of KASPER effectiveness, a stratified population of KASPER requestors and providers has been identified.

b. For the 2004 Hal Rogers Grants, a final report was to be submitted to the DOJ by June 30, 2005. We would like a copy of this report.

Answer. The 2004 Hal Rogers Grant is anticipated to be completed December 31, 2004, at which time the final report will be due. A semi-annual progress report for the period January 1 – June 30, 2005 was due July 31, 2005. That is the Phase I Findings and Recommendations Report that was submitted on July 29. A copy of the report will be provided to you.

c. For 2005, a Hal Rogers Grant application has been submitted. What is the status of that application?

Answer. The 2005 grant application was submitted January 14, and we received notice on July 14 that the Cabinet was awarded the grant.

d. For the 2005 Hal Rogers Grant application, what were the objectives for the grant?

Answer. The 2005 grant identifies the following five objectives:

1. Use data housed in the system to highlight trends of suspect behavior.
2. Analyze associated business processes to ascertain if modifications need to be made.
3. Isolate technical issues that hinder system performance.
4. Improve methods for monitoring system access.
5. Design the means to monitor the system's efficiency.

Question 7. There are currently two bills in the Congress seeking to implement a national all schedule prescription monitoring system. What effect could this have on KASPER? What effect could KASPER have on the national program? For example, could KASPER be marketed to other states to offset costs and aid investigations across state borders?

Answer. KASPER is the model used for most new state programs. We have had several states send delegations to Kentucky to discuss KRS 218A.202 and see how we set our program up and how much support we receive from our user base as well as our law makers. There could be potential to market the eKASPER system to other states, as well as the possibility of running other state systems through the KASPER system. The key would be the legislation passed by other states.

Question 8. While there have been significant advances to KASPER, how can the current system be circumvented and what are potential solutions?

Answer. Taking controlled substance prescriptions out of state or submitting fraudulent data.

Question 9. What is the status of the Medicaid interface with KASPER and how will/does this system work? What has the level of success been in preventing/addressing problematic prescriptions? How can this interface be improved?

Answer. A Medicaid/eKASPER Integration (MeKI) prototype was completed on June 30, 2005. During a review of the prototype with investigators in the Programs Enforcement Branch, several issues and problems with the prototype functionality were identified. We are now researching how those problems can be addressed to determine whether the prototype can be modified to provide a temporary investigation tool until a production system can be implemented, or whether the results of the prototype will serve only to define the requirements and design for development of the production system to accomplish the Medicaid/eKASPER Integration. Investigators will need to continue to use manual processes to identify Medicaid recipients with a high probability for abuse, until the prototype can be made functional or a production system can be implemented to automate this process.

Question 10. Is the KASPER system useful (or will it be useful) to the Medicaid program? KRS 218A.202 allows Medicaid to use data or reports from KASPER to identify "Medicaid recipients whose usage of controlled substances may be appropriately monitored by a single outpatient pharmacy or primary care physician."

Answer. Authorized members of the Division of Fraud, Waste & Abuse Identification & Prevention have had access to the KASPER system for several years, using KASPER reports on a regular basis as a tool in their investigations. Changes to the statute have increased the ability for Medicaid personnel to share the data, for example with law enforcement officials engaged in a bona fide specific investigation, and with licensure boards.

Question 11. Could the KASPER system benefit from sharing information with the Medicaid program, e.g., from KAMES or the MMIS? Could such data be legally accessed by KASPER? How might KASPER users find such information useful?

Answer. The current statutes allow the sharing of Medicaid data with authorized KASPER users within the Department for Medicaid Services. (See the information regarding the Medicaid/eKASPER Integration Prototype in question 9 above.) However, there is no statutory authority for authorized KASPER users (such as physicians and pharmacists) to have access to the Medicaid data. Authorized KASPER users with questions or concerns regarding information in their KASPER reports related to Medicaid recipients should contact an investigator in the Division of Fraud, Waste & Abuse Identification & Prevention.

Question 12. What revisions or additions to statute and/or regulation do you think need to be made to further enhance the usefulness of KASPER? What deletions from statute and/or regulation need to be made? Please explain.

Answer. Required utilization of a standardized patient identifier would greatly enhance the KASPER program. This would require a language change to require a court order to be for criminal proceedings only.

Question 13. What else would you like to tell us about KASPER that would make the Program Review study report more useful to readers?

Answer. KASPER should be thought of as a ***tool*** to be used by medical professionals and law enforcement personnel to help intervene with those who misuse or abuse prescription drugs and to decrease the diversion of legal controlled substances in the Commonwealth.

7 Program and Project Support for KASPER

KASPER is supported by both federal and state initiatives and funding. This section describes these support programs and their impact on the development and ongoing operation and enhancement of the program. Federal support for KASPER currently is provided under the Hal Rogers Grants. Kentucky received $350,000 enhancement grants for fiscal years 2004 and 2005, and has applied for a fiscal year 2006 enhancement grant for $400,000. State funding is provided by the legislature. In addition to the funding appropriated to build the original KASPER system and the Web-based eKASPER system, the legislature in 2004 appropriated a $5 million capital construction budget for the eKASPER System Upgrade Project to upgrade and enhance the eKASPER system.

Hal Rogers Grant funding is primarily used for the following purposes:

- education and training efforts,
- organizing and facilitating focus and working groups that provide guidance on user requirements and enhancements to KASPER,
- conducting KASPER user satisfaction surveys,
- conducting prescription drug data analysis,
- participating in national organizations supporting PMPs, and
- communicating with other states to share program information and experiences and to investigate how we can share PMP data with other states.

Capital construction project funding is primarily used for the following purposes:

- maintenance and enhancements to the system infrastructure (hardware and software),
- professional services to operate and maintain the system,
- professional services to develop enhancements to the system,
- professional services to develop system interfaces, and
- construction and related costs for the DEPPB office relocation.

7.1 2003 Prescription Drug Monitoring Program Grant

During the 2002 Kentucky General Assembly, HB 26 amended KRS 218A.202 to direct the Governor's Office for Technology (now the Commonwealth Office for Technology) in consultation with the Cabinet for Health Services (now CHFS) to submit an application for a federal drug diversion grant to fund a pilot project to study a real-time electronic monitoring system for Schedules II, III, IV, and V controlled substances. The statute indicated the pilot project shall:

a) Be conducted in two (2) rural counties that have an interactive real-time electronic information system in place for monitoring patient utilization of health and social services through a federally funded community access program; and
b) Study the use of an interactive system that includes a relational data base with query capability.

A 2003 Federal Prescription Drug Monitoring Program Grant was awarded to the Commonwealth Office of Technology (COT) to complete the pilot project. In August 2003 COT awarded a contract to VPSH Holding, LLC to conduct a pilot real-time electronic prescribing (e-Prescribing) system project in two rural Eastern Kentucky counties. In March 2004 COT engaged the University of Louisville School of Public Health and Information Sciences to conduct an assessment of the pilot project and report the findings in an Assessment Report. The final Assessment Report was submitted in April 2005. The Executive Summary from the Assessment Report is reprinted below.

7.1.1 KASPER and e-Health Study

The grant used to fund the Prescription Drug Monitoring Pilot referenced above had funds remaining after completion of the pilot and the assessment report. On November 18, 2005 COT received a 12 month extension of the grant to utilize the remaining funds to promote efforts to further enhance Kentucky's prescription drug monitoring efforts. COT is now in the process of implementing a Memorandum of Agreement authorizing the University of Louisville School of Public Health and Information Sciences to perform a study of e-Health (electronic health information) systems and their implications for KASPER. It is anticipated the study will focus on:

1. Integrating KASPER with evolving electronic prescribing technology; including specific privacy concerns, infrastructure issues and funding issues, and recommended solutions.
2. Electronic controlled substance prescription information collection and reporting, both opportunities and barriers related to timeliness and accuracy; including specific privacy concerns, infrastructure issues and funding issues, and recommended solutions.
3. Exploring the feasibility of combining eKASPER data management and the e-Health Network Board initiative on prescription drug tracking (medication history) identified in SB 2 Section 4.

(Refer to section 11.1 KASPER and e-Health for more information about the Kentucky e-Health initiative.)

7.1.2 Prescription Drug Monitoring Pilot Results

The Prescription Drug Monitoring Pilot allowed assessment of the pros and cons of implementing an e-Prescribing system in Kentucky. The pilot assessment also described how implementing an e-Prescribing system statewide could provide a method for obtaining controlled substance prescription data in a real-time mode. While the pilot was also intended to demonstrate the feasibility of using an e-Prescribing system as a PMP as well, the study results do not go into detail on how that could be accomplished as either a replacement for KASPER or as an enhancement to KASPER. It should also be noted that discussions and references to KASPER in the pilot referred to the original paper and fax version of KASPER. eKASPER was under development during the time frame of the study, and was implemented just prior to publication of the Assessment Report. Following is the text of the Assessment Report Executive Summary reflecting the high level results and conclusions drawn from the pilot.

Prescription Drug Monitoring Pilot - Assessment Report Executive Summary[5]

"The purpose of this report by the University of Louisville School of Public Health and Information Sciences is to assess for the Commonwealth of Kentucky the VERISCRIP™ system as installed at two pilot sites in Eastern Kentucky. VERISCRIP™ is a real-time electronic prescribing system using a back-end data repository with reporting capability that has been proposed by the vendor for use as an electronic controlled substance prescription monitoring and reporting system, or as a system enhancement for existing systems. Kentucky law currently requires pharmacies and other dispensing agencies to report controlled substance prescriptions at least every two weeks, and requiring the use of an electronic prescription system for all controlled substance prescriptions would require a change in the law.

The VERISCRIP™ system was evaluated within two major contexts: 1.) the historical activities of federal and state agencies to monitor controlled substance prescriptions; and 2.) the rapidly evolving national and state health information infrastructure initiatives that have the future potential to significantly enhance the type and accuracy of electronic health information and its real-time availability.

[5] The School of Public Health and Information Sciences, University of Louisville; *Prescription Drug Monitoring Pilot Assessment Report,* April 25, 2005

Potential benefits and advantages of the VERISCRIP™ system and concept for Kentucky were assessed in comparison to the KASPER system operational at the time of the pilot. Enhancements to the KASPER system, such as the development and implementation of "enhanced KASPER" in March 2005, were not considered in this assessment. *(Emphasis added by document author.)*

The report identifies areas of shared interest, and potentially significant conflicts of interest, among stakeholders on the regulatory and healthcare sides as it relates to controlled substance prescription monitoring and reporting. In addition, the report identifies a number of areas where new or modified policies would be required to ensure that any initiative involving controlled substance prescription ordering and tracking has appropriate oversight, is implemented in the smoothest way possible, is fair for all participants, and protects all parties and their health information.

The pilot technology was designed to demonstrate the feasibility of using an electronic prescription system with physician order entry technology as a controlled substance prescription monitoring and reporting system. The system requires the prescribing physician to key controlled substance prescriptions into a PC, print out a bar-coded paper prescription, and the pharmacist to authenticate the paper prescription when presented by the patient by verifying it against the original electronic version in the system's data repository. This process means that controlled substance prescription information could thereby be made available in real-time to those authorized access by law.

The pilot demonstrated this capacity at the two pilot sites where it was installed. The pilot was not intended to demonstrate statewide scalability. The core technological platform is provided by a major electronic prescribing system provider and, based on representations made by the VERISCRIP™ Vendor, the technology appears scalable. Evidence, such as database schematics, was not provided to permit a scalability assessment. Although it may be technologically scalable to a statewide system, it is not clear how- or whether- interoperability, organizational and political issues could be effectively addressed to support a statewide implementation.

The pilot system required additional data-entry time by prescribing practitioners (an additional 3.5 minutes per prescription on average), but this data-entry time could be reduced over time through improved data entry short cut programming and integration with computerized electronic health record and other practice systems. Over time, there should also be other productivity gains that offset increased data-entry time for prescribing practitioners.

The VERISCRIP™ vendor proposes to charge the state an approximate $4 million one-time licensing fee, and a transaction fee structure that will cost an estimated $4 million per year once all controlled substance prescribing and dispensing practitioners statewide are using the system. The costs for prescribing practitioners are significant. One-time direct costs are estimated at $8.5 million total, or an average of $3,530 each. Indirect costs (costs for lost productivity) are estimated at $6,000-$12,000 per prescribing practitioner per year for the first year. These indirect costs will decrease over time, however, with the potential for measurable benefits to outweigh indirect costs within 5-6 years. Costs for regulators and dispensing practitioners to be trained and use the system are nominal. These cost estimates are based on mandated use of the system by all controlled substance prescribing and dispensing practitioners.

There was strong, unanimous stakeholder support for the proposed concept because of the real-time access to controlled substance prescription information. There is the belief that such a system would reduce the diversion of controlled substance prescription drugs to illicit use and reduce harm to patients. Stakeholders interviewed felt strongly about the need for, and benefits of, such a system. However, stakeholders expressed concern about the burden on prescribing practitioners of "another unfunded mandate". Some stakeholders felt this burden and the costs of the system were worth the availability of real-time information. Others felt they were not. Pilot system users expressed strong concern about the productivity costs of using the system as installed and working at the pilot sites. When asked "would you recommend the use of this

system for other prescribing physicians?" most answered along the lines of "no, not the way it works now - it takes too much time."

In conclusion, the concept and technology have promise, and could potentially add significant value to the effort to address drug diversion by making available real-time controlled substance prescription information. The major barrier to implementation would be resistance by prescribing practitioners and others concerned about the unfunded productivity costs and opportunity costs in the context of emerging health information exchange technologies. The state must address whether the cost is worth the benefit at this time – and if so, whether the political capital is available to convince practitioners and legislators to support the mandate."

7.2 Hal Rogers Grants

7.2.1 Hal Rogers Grant General Information

In FY 2002 the U.S. Department of Justice Consolidated Appropriations Act (Public Law 107-77) created a grant program entitled Developing and Enhancing Prescription Drug Monitoring Programs. The grants have become known as the Hal Rogers Grants, in honor of primary sponsor of the act, Congressman Harold (Hal) Rogers from Kentucky's 5th Congressional District. The Bureau of Justice Assistance administers this program with the U.S. Drug Enforcement Administration (DEA), Office of Diversion Control and the Office of National Drug Control Policy (ONDCP). Appendix G. Organizations Associated with Prescription Monitoring Programs provides a brief description of these agencies

The primary purpose of the grant program is to enhance the capacity of regulatory and law enforcement agencies to collect and analyze controlled substance prescription data through a central database administered by an authorized state agency. The program focuses on providing help for states that want to establish a PMP and to help states with existing PMPs to improve the efficiency and effectiveness of the program. Program objectives include:

- Building a data collection and analysis system at the state level.
- Enhancing existing programs' abilities to analyze and use collected data.
- Facilitating national evaluation efforts.
- Encouraging the exchange of information and collected prescription data among states.
- Assessing the efficiency and effectiveness of programs funded under this initiative.
- Enhancing collaborations with law enforcement, prosecutors, treatment professionals, the medical community, and pharmacies.

<u>Award Categories</u>

States may submit a grant application in one of three categories:

- CATEGORY I: PLANNING. Grant maximum: $50,000. Project period: 15 months.
  - States without a PMP may apply for a planning grant, and need not have legislation or regulations pending or in place.
- CATEGORY II: IMPLEMENTATION. Grant maximum: $400,000. Project period: 24 months.
  - States that have in place or pending legislation or regulations that require the submission of dispensing data to a centralized database *and* authorize and/or designate a state agency to provide program oversight and implementation may apply for an implementation grant. States developing a voluntary pilot program also may apply for an implementation grant. Funds may be used to plan, establish, and build a data collection and analysis system; develop an infrastructure to support programmatic activities; facilitate the exchange of information and collected prescription data among states; facilitate the establishment of collaborations; produce

and disseminate educational materials; and assess the efficiency and effectiveness of the program.

- CATEGORY III: ENHANCEMENT. Grant maximum: $400,000. Project period: 24 months.
  - States seeking to improve existing PMPs for diversion efforts are eligible to apply for an enhancement grant. Funds may be used to enhance a data collection and analysis system; develop infrastructure to support programmatic activities; support collaborations with law enforcement and prosecutors; facilitate information sharing among states; and assess the efficiency and effectiveness of the program. Enhancement applications should not be used to chiefly support core programmatic activities.

Eligibility

State governments are eligible for grant funds if they have in place or pending an enabling statute or regulation that requires the submission of controlled substance prescription data to a centralized database administered by an authorized state agency. The legislation or regulations should include:

- The required submission of data for prescriptions in Schedules II, III, IV, and V.
- The submission of data elements consistent with standards established by the American Society for Automation in Pharmacy.
- Access to collected data by federal, state, and local law enforcement personnel statutorily authorized to access prescription data by traditional, manual methods.

7.2.2 2004 and 2005 Hal Rogers Grants

The 2004 and 2005 Hal Rogers Grants are being used to help improve the efficiency and effectiveness of KASPER. The 2004 grant period is from May 1, 2004 to April 30, 2006. The 2005 grant period is from September 1, 2005 to November 30, 2006. Because many of the objectives under the grants include activities that are ongoing or span the duration of both grants, the following discussion reflects the status and results of activities being performed under both grants. The 2004and 2005 grant objectives included the following.

- Charter Focus Groups.
- Generate a KASPER Satisfaction Survey.
- Conduct Independent Objective Data Analysis.
- Educational Outreach and Intervention Education.
- Conference Attendance.
- Develop and Test a Medicaid/eKASPER Interface (MeKI) Prototype.
- Isolate and Address Technical Issues.
- Verify User Credentials Periodically.
- Create System Performance Reports.
- Develop Trend Reports.
- Streamline Business Processes.

Following is a summary of the progress and outcomes of the 2004 and 2005 Hal Rogers Grant activities.

7.2.2.1 Focus and Working Groups

The 2004 Hal Rogers Grant project team assembled two interdisciplinary focus groups comprised of law enforcement and health care professionals. Each focus group met twice to discuss a broad range of issues related to the diversion, misuse, and abuse of pharmaceutical controlled substances. From those groups,

representatives from law enforcement and professional licensure organizations were asked to participate in working groups to discuss investigative issues related to pharmaceutical controlled substance diversion, abuse, and misuse as well as technical and reporting issues relevant to the KASPER system. A list of the groups and participants can be found in Appendix I. Hal Rogers Grant Focus and Working Group Participants. Recommendations impact five distinct communities:

1. Professional Licensure Boards,
2. Health Care Providers,
3. Law Enforcement,
4. Cabinet for Health and Family Services, and
5. General Public.

The work of the Focus and Working Groups is complete. Many of the recommendations have already been implemented, while others are planned for further investigation and/or future implementation. Several of the recommendations fall outside the scope of the grant. The recommendations are detailed below.

Recommendations Impacting Licensure Boards

Conduct a Retrospective Study on the KASPER Database

The Kentucky Legislature authorized the Kentucky Board of Medical Licensure (KBML) to receive trend reports based upon the data housed in the KASPER system. In order to meet the legislature's request, the group recommended that a retrospective study of the KASPER database be conducted to determine what trends exist and the frequency at which those trends need to be monitored to detect change over time. The retrospective study would develop a baseline from which changes in trends can be monitored. After developing a baseline for the state, trends to be studied include:

- Geographic distribution of prescribing patterns based on five-digit zip code and county,
- Analyze changes periodically,
- Identify outliers by specialty within region,
- Compile prescribing aggregates by region and specialty, and
- Design drug "cocktail" reports to identify prescription combinations by practitioner, region and specialty.

A retrospective study is crucial to identifying the trends to be reviewed regularly by the Cabinet for Health and Family Services and the KBML. The group recommended that the Cabinet use an independent source of data analysis (e.g. Kentucky Injury Prevention and Research Center) to complete the retrospective study.

Status: The OIG is working with the KBML, as well as the Kentucky Board of Pharmacy, Kentucky Board of Dentistry, and the Office of Drug Control Policy (ODCP) to determine a base set of trend reports to be provided to the regulatory boards and ODCP, including a set of retrospective trend reports based on 2003 – 2005 KASPER data. This effort is described in more detail in section 7.2.2.10 Develop Trend Reports. In addition, the OIG contracted with the Kentucky Injury Prevention and Research Center (KIPRC) to perform a baseline study on KASPER data for 2000-2002. This report contains the data analysis that will form the baseline for future retrospective prescription drug analysis studies. The results of the study performed by KIPRC are described in detail in section 8.2 Retrospective KASPER Data Analysis.

Encourage Investigative Interstate Compacts among Professional Boards

Currently, there exist some interstate liaisons between various professional boards in order to verify licensure information. The Kentucky Board of Nursing has expanded upon this by creating a model compact that

allows for joint investigations as well as other licensure matters. Other professional boards use several national data banks. While such liaisons and data banks are invaluable, they do not constitute a definitive, organized compact among professional boards for the singular purpose of addressing cross border pharmaceutical drug abuse and diversion. Therefore, the Investigations Working Group recommended that interstate compacts be developed between licensure boards for investigative purposes.

Status: It was determined to be outside the scope of the grant to establish, coordinate or maintain investigative compacts among professional boards. As efforts progress toward establishing relationships with other states to promote sharing of PMP data, the intent is to support and assist with the states in developing processes that will foster these types of interstate compacts between regulatory boards.

Study How KASPER Reports are used in the Field

Law enforcement and health care providers request KASPER reports; however, there is currently no information on how the reports are used after the requestor has received them. Part of the thrust of this initiative is to educate health care providers and law enforcement about the appropriate uses of KASPER reports. After the appropriate educational components are in place, it is recommended that a follow up survey be done to determine if the providers and law enforcement communities are utilizing KASPER reports appropriately; i.e., analyzing the data for potential misuse and/or abuse; recommending appropriate addiction treatment, and referring diverters to the appropriate authorities when necessary.

Status: Questions regarding use of KASPER reports in the field were included in the design of the survey booklet for the 2006 KASPER Satisfaction Survey. In addition, plans include gathering this type of report usage information via the Web-based survey capability to be developed under the eKASPER System Upgrade (Phase II) Project.

Recommendations Impacting Health Care Providers

Require Positive Patient Identification on Controlled Substance Prescriptions

In order to reduce inaccurate information that may reach the KASPER system, the Technical Specifications Working Group recommended that prescribers be required to put the patient's date of birth and associated identification number (such as a driver's license number, Medicaid identification number, etc.) on the prescription. Occasionally when family or friends have a prescription filled for another, they do not know the patients' identification number or date of birth. As a result, pharmacies sometimes receive inaccurate information that is passed on to the KASPER system during the prescription reporting process.

Status: While current regulations governing KASPER do not mandate positive identification for every controlled substance prescription, efforts are underway to modify the existing KASPER regulation to strengthen the identification and reporting requirements. Refer to section 6.4 Proposed Regulation Changes – 902 KAR 55:110.

Disseminate Descriptions of the Typical Behaviors Associated with Controlled Pharmaceutical Provider Shopping to Health Care Providers

Working group participants agreed that many health care providers do not know the behaviors typically associated with controlled pharmaceutical provider shopping. As a method to remedy this problem, the group developed a chart including descriptions of these behaviors, to be shared with health care providers throughout the Commonwealth. The participants also identified characteristics of health care providers that may cause a provider to be targeted by individuals engaged in pharmaceutical controlled substance provider shopping. These characteristics include:

- New providers,

- Senior providers,
- Diet clinic providers,
- Providers who are perceived to keep substandard records, and
- Pain management providers.

Status: The provider shopping behavior chart has been incorporated into the KASPER Provider Brochure and the KASPER Law Enforcement Brochure as well as the KASPER training presentation for health care professionals, along with the characteristics of targeted health care providers. The provider shopping behavior chart is also utilized in appropriate newsletter and trade journal articles for health care professionals. The chart is included as Appendix A.1 Typical Doctor Shopping Patient Behaviors.

Develop Training for Health Care Providers on Conducting Brief Interventions

One issue highlighted in the focus group discussions of pharmaceutical addiction was that many health care providers are not equipped with the appropriate tools to conduct brief interventions when needed. In order to alleviate this problem, it was recommended that a seminar on brief interventions be developed. The group envisioned a two hour course accredited for continuing education units (CEU).

Status: An intervention component was developed and integrated into a KASPER training session to be offered to health care professionals for Continuing Education Units. Refer to section 9.2 Continuing Education for Health Care Professionals for a detailed description of the training developed.

Educate Law Enforcement and Health Care Communities about KASPER

The Education Working Group agreed that the primary audience for KASPER educational outreach should be practicing professionals. The secondary audience should be professional students with the point of entry being curriculum (dental, medical, pharmacy, nursing and law enforcement). The following methods for disseminating information about KASPER to health care provider and law enforcement communities were identified:

- Develop a speaker's bureau comprised of peer groups to give 30-45 minute KASPER presentations at professional staff meetings and/or conferences,
- Sponsor a booth at professional meetings to explain KASPER and distribute brochures,
- Develop professional newsletter articles,
- Develop professional journal articles,
- Design a Web download,
- Design and distribute a one page laminate.

Status: Rather than develop a speaker's bureau, the OIG is utilizing existing staff to conduct in-person presentations and training for health care professionals, law enforcement officials, and health care students as part of their training curriculum. OIG staff sponsors a KASPER exhibit at appropriate professional trade shows and conferences to increase awareness and usage of KASPER. In addition, OIG is working to implement Web-based training that should preclude the need for a speaker's bureau. OIG intends for the Web-based KASPER training to include the capability to download KASPER literature, and selected literature will also be made available in downloadable format on the KASPER Web site. OIG has developed a KASPER brochure for health care professionals that is distributed instead of a one page laminate. Refer to section 9 KASPER Education and Training for a detailed review of education and training development efforts and materials.

Recommendations Impacting the Law Enforcement Community

Increase Investigative Staff and Provide for Consultant Fees

The Investigations Working Group identified staffing limitations and lack of funds for consultant fees, to be two of the most critical issues facing organizations involved in investigating the abuse, misuse, and diversion of pharmaceutical controlled substances. Currently, the Drug Enforcement and Professional Practices Branch has a total of 4 investigators throughout the state. In 2004, the DEPPB conducted over 240 investigations and received an average of 12-15 complaints per day. Not every complaint received generates a full investigation; however, each complaint must be reviewed to determine if it is valid and if an investigation is warranted.

Between FY2000 and present, Drug Enforcement Administration (DEA)-Diversion has worked approximately 55 criminal cases against medical professionals. Of those, approximately 52 were worked jointly with state agencies. The DEA also worked 82 administrative cases between FY2000 and present. In addition to their investigative duties, the DEA conducts regulatory inspections. The DEA conducted 86 regulatory inspections between FY2000 and present. Each inspection requires approximately 40 hours from at least one investigator; therefore, the DEA loses a minimum of 720 investigator hours to yearly regulatory inspections.

Representatives of the DEPPB and the DEA stated that often they refer cases to other law enforcement agencies (such as the Kentucky State Police, local and regional drug task forces, etc) due to their staffing constraints. The table below lists some of the agencies that commonly receive complaints regarding pharmaceutical controlled substance abuse and diversion. For each agency, the table provides the number of investigators on staff, the number of complaints received per month, and the additional staffing needs. The table below clearly illustrates that each agency listed has an over-allocated investigative staff.

Organization	Complaints per month	Current Investigative Staff	Additional Staffing Needs
DEPPB	250	4[6]	2
DEA	40	6[7]	6
Kentucky Board of Medical Licensure (KBML)	21 (8-10)[8]	5	1
Kentucky Board of Nursing (KBN)	101 (18)[8]	4	1
Kentucky Board of Dentistry (KBD)	12-13 (2-3)[8]	2 part time	1 part time
Kentucky Board of Pharmacy (KBP)	10 (1)[8]	4	

With the recent advances to the KASPER system, the group expects the number of complaints received to rise significantly. Between the current workload and the projected additional complaints resulting from the enhanced KASPER system, the current staffing shortage will reach critical levels. Therefore, the additional staffing needs listed in the table above is a crucial first step in addressing the significant investigative staffing shortage present in the pharmaceutical controlled substance diversion area. When investigators at the professional licensure boards develop a case, often they need to have the details of the case reviewed by another professional in the same discipline. As a result, each of the boards has consultants who help them review cases. These consultants charge $50 to $85 per hour and can cost agencies as much as $3000 for a single investigation. Consultant fees make up a large part of the budget needed by professional licensure

[6] As of February 1, 2006, the DEPPB investigative staff numbers 3, reflecting a need for 3 additional staff.
[7] The number of DEA investigators is limited to those working within Kentucky.
[8] The number in parentheses indicates the number of complaints related to pharmaceutical controlled substance diversion and abuse.

boards to investigate provider diversion cases; therefore, the group recommended that more money be budgeted to consultant expenditures.

Status: It was determined that it is beyond the scope of the grant to increase investigative staff and provide for consultant fees for the agencies listed above.

Conduct Monthly Drug Diversion Investigators Meetings

Due to the overlapping nature of the criminal activity associated with pharmaceutical controlled substance diversion, the working group participants suggested that a monthly Drug Diversion Investigators meeting be established. The goal of this meeting would be to bring together investigators from all of the agencies that conduct pharmaceutical controlled substance diversion investigations to discuss cases. This interdisciplinary approach to information sharing would help prevent duplicate efforts across agencies and heighten awareness of especially troublesome cases and emerging trends in drug diversion.
The participants recommended that the following agencies be involved:

- Drug Enforcement Administration (DEA)
- DEPPB
- Louisville Metro Police Narcotics Unit
- Lexington Division of Police Narcotics Enforcement Unit
- UNITE
- Kentucky Bureau of Investigation
- Kentucky State Police
- Office of the Inspector General (OIG)
- Drug task forces from throughout the state

In order to incorporate the various drug task forces from across the state, the meeting may need to be split into regional meetings that include at least one constant representative from the OIG, DEA, or DEPPB.

Status: It was determined to be beyond the scope of the grant to coordinate this type of drug diversion investigators meetings. Instead, the grant team recommends that existing organizations such as the National Association of Drug Diversion Investigators (NADDI) be utilized to foster this type of cooperation and coordination among investigative agencies.

Streamline the Investigative Process by Using Summary Statistics

Implementation of the KASPER system has greatly reduced the time involved in investigating pharmaceutical drug diversion related cases. This is true because KASPER is a tool that helps investigators to identify where evidence may be located. Investigators use KASPER reports to narrow the scope of their investigations to the pharmacies where prescriptions related to the case have been filled rather than needing to review prescription information at every pharmacy or dispensing location in a large area. The Investigations Working Group identified several summary statistics that may be useful in streamlining the investigative process. Currently, data to calculate these summary statistics are housed in the KASPER database, but the calculations are not completed. The group recommended adding summary statistics to both prescriber and patient reports in order to help investigators clarify where to begin their investigations. Summary statistics for prescribers that may be retrieved from KASPER include:

- Average number of dosage units per substance per patient
- Average number of dosage units prescribed per substance based on specialty
- Total number of scripts dispensed per provider classified by specialty
- Average length of prescription based on specialty

- Average birth dates of practice based on specialty
- Expired or retired DEA numbers

The following summary statistics for patients may be retrieved from KASPER:

- Early refills
- Number of prescribers per specialty
- Multiple addresses

Status: The OIG plans to review this recommendation with the DEPPB and KASPER development teams, to determine if it would be beneficial to include these statistics on appropriate reports.

Provide Investigators a Typical Behaviors List for Pharmaceutical Diversion Activity

The Investigations Working Group developed a chart listing typical behaviors associated with provider diversion. This list is not meant to be used to stigmatize individuals or groups, but rather is intended to be a useful tool for both criminal investigators in law enforcement and administrative investigators representing the professional licensure boards. The group recommended that the chart be provided to investigators working in the area of pharmaceutical drug diversion. In addition, the working group participants identified a few types of practices that seem to have a higher incidence rate of provider diversion than others. Those include:

- Diet practices,
- Pain management practices, and
- Practices owned by non-healthcare professionals.

The group recognized that not all practices in these three categories are involved in inappropriate behavior; however, these types of practices have been recognized by law enforcement and professional peer groups as potential havens for providers involved in controlled substance diversion.

Status: The provider diversion chart has been incorporated into the KASPER Law Enforcement brochure as well as the KASPER training presentation for law enforcement officials. The chart is included as Appendix A.2 Typical Behaviors of Diverting Providers.

Recommendations Impacting the Cabinet for Health and Family Services

Develop a Phased Approach to Reaching Real Time Data Collection

Some of the barriers to collecting and reporting data in real time are the technology limitations of some pharmacies within the Commonwealth. In an attempt to mitigate this issue, the Technical Specifications Working Group recommends that a phased approach to real time data collection be implemented. Representatives agreed that a phased approach would allow pharmacies ample time to modify current systems or purchase new systems that would have the capacity to collect and transmit data to KASPER in real time. The approach recommended by the group is detailed below:

Phase	Description
Weekly	Pharmacies throughout the state would batch data weekly and send the information to the data collection agency thus allowing data to be loaded into the KASPER database no more than ten days from the date the prescription was filled.
Bi-Daily	Batching data every other day and sending the information to the data collection agency allows prescription information to be entered into the KASPER database within 3 business days of dispensing

Daily	Pharmacies would batch data daily and provide the information directly to KASPER allowing prescription information to reach the database within 36 hours of dispensing.
Real-Time	Prescription data from each transaction would be immediately loaded into the KASPER database, similar to the methods used by third party payers currently.

Status: A regulation change is being promulgated that would require pharmacy reporting every 8 days. Refer to section 6.4 Proposed Regulation Changes – 902 KAR 55:110. In addition, the OIG is working with the Office of Information Technology to develop a Request for Proposal (RFP) for real-time prescription data collection. Based upon preliminary discussions with vendors processing prescription drug claims for insurance companies, we believe it may be possible to utilize one of these vendors to capture the majority of Kentucky controlled substance prescriptions during benefit validation at the time the prescription is being dispensed. Data for controlled substance prescriptions not processed by these vendors would still need to be accomplished through existing processes. Capturing a significant amount of prescription data in this manner would constitute a major step toward approaching real-time prescription data collection. (Refer to section 7.3 eKASPER System Upgrade (Phase II) Project for more information regarding real-time data collection.)

Develop Interstate Compacts among Prescription Monitoring Programs

Participants discussed the migration of drug seeking behavior from one state to another. Migrating drug-seeking behavior outside of Kentucky does not alleviate the problem within the Commonwealth because only the associated behavior is moved, not the drug seeker. The problems associated with drug seeking individuals include the need for treating substance abuse, the misuse of public assistance programs such as Medicaid and Disability, loss of productivity, and potential criminal behavior. These problems do not migrate out of the Commonwealth as individuals seek controlled substances in border states because usually the individual does not change their state of residence; therefore, it is imperative that law enforcement agencies be able to easily and readily retrieve information across state lines.

Currently, twenty one states have some type of PMP and three more have passed legislation to create a program. In order to tap into the resources in Kentucky's surrounding states, the Investigations Working Group recommends developing interstate compacts that can address all of the issues surrounding sharing confidential information maintained in PMPs.

Status: The realization of this recommendation will ultimately depend upon willingness and ability of neighboring states to participate in interstate compacts designed to share information maintained in PMPs. The OIG plans to take a leadership role including contacting PMP administrators in our border states to begin discussions on the processes and systems that would be needed to allow sharing of PMP data between states.

Recommendations Impacting the General Public

Mandate that Positive Identification for Pharmacy Signature Logs be Required

Currently there are no mandated criteria for retrieving a controlled substance prescription. While the working groups did not suggest limiting who is eligible to pick up controlled substance prescriptions, they did recommend that the individual picking up a controlled substance be required to show positive identification and print and sign a signature log. While this may not deter the most determined diverters, it will raise awareness among the general population to the problem of controlled substance diversion. The accurate signature logs would also be vital in investigations where diversion, theft and/or fraud have been reported.

Status: Current regulations governing KASPER do not mandate positive identification for every controlled substance prescription. A regulation change is being promulgated that would include more stringent

requirements for positive identification. Refer to section 6.4 Proposed Regulation Changes – 902 KAR 55:110.

Educate the Public about Controlled Pharmaceutical Addiction and KASPER's Uses

As a publicly funded program, it is the Cabinet's responsibility to educate the public about the uses and benefits of the KASPER program. KASPER was put in place to combat the Commonwealth's controlled pharmaceutical substance abuse, addiction and diversion issues. One of the best methods to combat this abuse and addiction is to raise the public's awareness by providing information about the nature of controlled pharmaceutical addiction and how KASPER is used to aid health care providers in identifying potential abuse and addiction patterns. As a result of this, the working groups recommended that an informational brochure be distributed to the public.
The brochure should include information concerning:

- Where to find assistance if the individual, their family or friends may have a controlled pharmaceutical substance issue,
- Patterns and behaviors associated with abuse and addiction, and
- KASPER's history and uses in the fight against abuse, addiction and diversion of controlled pharmaceutical substances.

A Public KASPER Brochure has been developed. The brochure focuses on understanding and identifying prescription drug addiction problems, and identifying resources for assistance. The brochure is distributed at public meetings such as civic organizations, and other appropriate public venues, as well as being made available to pharmacies to distribute to their customers.

Conduct Cost Analysis of Controlled Pharmaceutical Addiction

It is rumored that controlled pharmaceutical addiction costs the Commonwealth, businesses, and individuals millions of dollars each year. In order to determine full extent of the costs associated with these issues, the groups recommended that a full cost analysis be completed.
A cost analysis study should include, but not necessarily be limited to, the following measures:

- Lost wages,
- Worker's compensation,
- Prosecution and incarceration costs,
- Treatment,
- Loss of productivity due to use of sick days and/or injury on the job,
- Health care costs due to other medical conditions that arise from the addiction, and
- Cost to the health care system due to the extra time and effort required dealing with addiction behavior.

Status: It was determined that this type of cost analysis study is outside the scope of the grant.

7.2.2.2 Generate a KASPER Satisfaction Survey

The 2004 KASPER Satisfaction Survey was launched in October 2004 to gather the opinions of the KASPER user community, to assess user satisfaction and to evaluate the usefulness, effectiveness and efficiency of KASPER as a tool for health care professionals and law enforcement officials in the fight to prevent the diversion of prescription medications. The survey implementation was concluded in June 2005. Results from the survey are being used to create recommendations for enhancements to the KASPER system and for the development of additional educational materials to address the needs of the user community. A full description of the survey background, methodologies, results and conclusions of the survey is available in section 8.3 2004 KASPER Satisfaction Survey.

7.2.2.3 Independent Objective Data Analysis

One of the working group recommendations was to conduct a retrospective study on the KASPER database, utilizing an independent source of data analysis, to provide a baseline for data comparison after the implementation of eKASPER and the educational initiatives implemented under the grant. The Cabinet contracted with the Kentucky Injury Prevention Research Center (KIPRC) to complete the initial data collection and analysis. A full description of the background, methodologies, results and conclusions of the study is available in section 8.2 Retrospective KASPER Data Analysis.

7.2.2.4 Educational Outreach and Intervention Education

Under the Hal Rogers Grants, the grant team has been heavily involved in KASPER education and training outreach through meetings, presentations, and training sessions with various associations. These meetings have provided invaluable opportunities to increase KASPER awareness on the part of health care practitioners, attorneys, judges, law enforcement officials and the public. These sessions have been used to market and train health care professionals and law enforcement officials on use of the eKASPER system, to educate attorneys and judges on the KASPER program, including the allowable use of KASPER data and reports, and to inform the public about the KASPER program and how they can recognize the signs when they or a loved one may be suffering from prescription drug addiction or abuse, and how they can seek help.

In addition, the grant team completed development of a KASPER training course for health care professionals that includes an intervention component. The course is being delivered in person in a presentation format, and we plan to make the course available as Web-based training on the University of Kentucky and University of Louisville Continuing Medical Education Web sites. A detailed description of KASPER education and training activities performed under the Hal Rogers Grants is included in section 9 KASPER Education and Training.

7.2.2.5 Conference Attendance

Members of the Hal Rogers Grant and KASPER teams actively participated in several key meetings related to PMPs and related topics.

1. The National Association for State Model Drug Laws (December 2-3, 2004)
2. The National Association of SURS Officials (August 21-24, 2005)
3. The Alliance of States with Prescription Monitoring Programs (October 17-18, 2005)
4. The National Association of State Controlled Substances Authorities (October 18-21, 2005)

These meetings provided an opportunity to establish relationships with PMP and compliance officials from several other states, and to begin discussions with PMP officials from some Kentucky border states regarding sharing of PMP data with those states. The grant team intends to continue to actively participate in these meetings to enhance our relationships with officials from other states and the federal government, and to provide members of these organizations with information about the capabilities and results we have achieved with KASPER. A description of these organizations is available in Appendix G. Organizations Associated with Prescription Monitoring Programs.

7.2.2.6 Develop and Test a Medicaid/eKASPER Interface (MeKI) Prototype

The 2004 Hal Rogers Grant included a Medicaid/eKASPER Interface (MeKI) Project to develop a prototype system to provide improved patient reporting for Medicaid Specialists in the Division of Fraud, Waste and Abuse Identification and Prevention. This prototype system uses an MS-Access database that merges data from the existing Medicaid databases and the eKASPER database to produce custom reports to replace current manual processes for reviewing the data. The MeKI prototype is a key component in efforts to

increase the long-term effectiveness and efficiency of the Kentucky Prescription Monitoring Program. Following are the objectives for the interface.

- Systematically provide a greater level of useful information to assist Medicaid Specialists in their efforts.
- Provide previously unavailable information to OIG and Department for Medicaid Services (DMS) management based upon the aggregation of Medicaid and eKASPER data.
- Improve the identification of controlled substance abusers who receive Medicaid.

Development of the MeKI prototype was based upon the following phased approach:

- User needs and business process analysis and documentation,
- Locating, retrieving and organizing Medicaid data,
- Locating, retrieving and organizing KASPER data,
- Merging and processing data to create the MeKI database, and
- Creating new reports for Medicaid Specialists.

Users of the system were interviewed and the information collected was used to create a set of business requirements for the new reports. Information was gathered about the previous business processes used in Medicaid reviews and fraud investigations. An investigator was shadowed in order to observe the actual processes in effect during actual investigations. In addition to end-user interviews, interviews of representatives from the OIG Division of Fraud, Waste and Abuse Identification and Prevention, the KASPER development team, the Drug Enforcement and Professional Practices Branch, First Health and UNISYS were conducted to provide additional background.

The MeKI reporting prototype system gathers data from the First Health Pharmacy Benefit Management (PBM) system, Medicaid Management Information System (MMIS), eKASPER and Hotline data systems into a single report to aid in the desk audits performed by Medicaid Specialists who are tasked with identifying Medicaid abuse and fraud.

A weighting system was devised by MeKI project analysts with the help of Medicaid professionals. This weighting system is designed to allow the Medicaid recipients who have characteristics of prescription drug abusers or fraud perpetrators to be identified and pulled quarterly from the First Health database. The weights are based on patterns identified as belonging to abusers and fraud perpetrators. The First Health weights for the recipients are loaded into the MeKI database.

Once the list of recipients is received by the MeKI administrator from First Health, those with weights of 50 or greater are sent to the Unisys MMIS data administrators in a request to pull claim detail data for the top 200 recipients that have not died, are not diagnosed with specific illnesses identified as not requiring review, and are not on Lock-in. The MMIS claim detail information is then loaded into the MeKI database. The ids, names and addresses of the 200 selected recipients are next provided to the eKASPER administrator and the Hotline data administrator in a request to pull that data for the 200 recipients. Once received, those data sets are also loaded into MeKI. Once the quarterly data has been loaded, the MeKI MS-Access database can be used to create reports for the investigators.

The MeKI prototype was completed on June 30, 2005 and delivered along with the following documentation:

- The MeKI Requirements Document containing the prototype data requirements, reporting requirements, run environment, risks and interdependencies, prototype variations from the requirements, system issues and future system recommendations, and
- The MeKI User Documentation containing an overview of the prototype, the quarterly data import process, the report generation process, and the application support functions.

Testing of the Medicaid/eKASPER (MeKI) interface prototype was conducted during July and August 2005. Members of the Medicaid Programs Enforcement Branch reviewed the interface prototype results and identified questions, issues, and recommended changes. The OIG worked with the developer of the prototype to answer the questions and determine how most of the issues could be resolved. The result of the prototype is a successful proof of concept that established the user requirements for the Medicaid/eKASPER interface, and provides a design model for the user interface and the investigative reports.

Development of the interface will not be completed under the Hal Rogers Grant. A new Web-based Kentucky Medicaid system called Interchange is currently under development, with a planned implementation date of November 2006. Based upon review of the completed MeKI prototype and estimates of the cost to implement the interface with the existing mainframe based Medicaid system, it was agreed that the most cost effective approach is to develop and implement the interface as part of the new Medicaid system, to be funded under the information technology capital project (refer to section 7.3 eKASPER System Upgrade (Phase II) Project). Joint Application Design (JAD) sessions are currently being conducted as part of the Interchange development project. Review of the interface prototype results and design of the Medicaid/eKASPER interface is planned to be completed during some of the scheduled JAD sessions.

7.2.2.7 Isolate and Address Technical Issues

In the 2005 grant application we identified the following anticipated KASPER technical issues:

1. lack of system availability,
2. poor performance due to system congestion, and
3. user comprehension of system tools.

Technical issues are currently being addressed by the CHFS Office of Information Technology (OIT), using funds from the KASPER capital project (refer to section 7.3 eKASPER System Upgrade (Phase II) Project). We plan to utilize grant funding to build upon our relationships with the KASPER user community via the KASPER focus groups, to confirm that these are technical issues affecting their ability to optimize use of the system, and to determine their priorities for addressing these issues. The Hal Rogers Grant team will also be involved in supporting the development effort, communication, and training (as appropriate) for new and enhanced KASPER system features and tools.

7.2.2.8 Verify User Credentials Periodically

User credential verification remains a key objective under the Hal Rogers Grants, in order to ensure that only authorized users have access to the information in KASPER, and to identify changes in the status of existing users that may require removal of their authorization. Our plans include working with Kentucky licensure boards and law enforcement agencies to focus on defining the specific requirements and methodology for periodic verification of user credentials.

7.2.2.9 Create System Performance Reports

The 2005 Hal Rogers Grant includes developing KASPER system performance reports to help the OIG quantify the effectiveness of the system. We identified the following information to be provided in system performance reports:

1. number of reports requested and completed per day,
2. number of manual and/or automated reports generated,
3. average delay from report request to delivery,
4. types of users on the system, and
5. number of reports requested by the different system users.

Some of this reporting is currently being completed on an ad hoc basis. Our plan is to review the proposed performance report criteria with system users and the KASPER development team, to validate that the information accurately reflects system performance and effectiveness, and to determine changes or additions to the proposed criteria. The OIG will then work with the Office of Information Technology to design and implement the system performance reports.

7.2.2.10 Develop Trend Reports

The 2005 Hal Rogers Grant includes development of KASPER trend reports. The grant team has conducted meetings with representatives from the Kentucky Office of Drug Control Policy (ODCP), Kentucky Board of Medical Licensure, Kentucky Board of Dentistry and Kentucky Board of Pharmacy to discuss the statutory requirements for KASPER trend reporting, and to establish an initial set of trend reports. (Trend reports were also discussed by the Hal Rogers Grant working groups as discussed in section 7.2.2.1 Focus and Working Groups, under the topic "Conduct a Retrospective Study on the KASPER Database".)

The initial trend reports provide statistical data in spreadsheet and GIS map form, reflecting county level data for the number of controlled substance prescriptions by patient address, and the number of controlled substance doses dispensed by patient address, for the following categories:

- all controlled substances,
- hydrocodone,
- methadone,
- morphine,
- oxycodone,
- diazepam, and
- alprazolam.

In addition to the number of prescriptions and doses, the reports include the year-to-year percentage change for trend identification purposes. These reports provide the KASPER team, the ODCP and the licensure boards with baseline trend data that will allow us to monitor controlled substance prescribing patterns over time. The trend reports also will be used to highlight potential problems with specific geographic areas or controlled substance categories, for further attention by the licensure boards and by law enforcement. While the standard KASPER trend reports do not identify any individual prescriber, dispenser or patient, based on these trend reports the Kentucky Board of Medical Licensure has the statutory authority to request additional KASPER reports that will allow them to identify possible problems with individual practitioners' prescribing practices. A set of standard trend reports will be created on a quarterly basis and sent to ODCP and the licensure boards. In addition, a GIS map representation of the data grouped into 6 reporting regions will be made available on the KASPER public Web site.

We are continuing to work with ODCP and the licensure boards to identify additional requirements and/or refinements to the reports to make them more useful, including reporting data by dispenser address, and modifying reports to reflect the data per 1000 of population to provide more meaningful comparisons between counties.

7.2.2.11 Streamline Business Processes

A major objective of the 2005 Hal Rogers Grant is to analyze and streamline the business processes for the Drug Enforcement and Professional Practices Branch (DEPPB), which is responsible for administration and operation of KASPER, and for enforcing the Kentucky Controlled Substances Act. The phenomenal increase in KASPER use since its inception in 1999 has created a critical need to examine and revise business procedures and practices in the DEPPB. We are utilizing the Office for Employee and Organizational Development (OEOD), a branch of the Kentucky Personnel Cabinet, to oversee this project. The project goals and scope were identified during October 2005, with the project kickoff conducted on November 2, 2005. OEOD personnel are currently in the process of reviewing existing business processes

and interviewing DEPPB staff members and stakeholders, to create as-is process maps and to identify potential areas for business process improvement. The as-is business process mapping is scheduled to be completed by the end of 1Q 2006. The next steps will be to develop recommended enhancements to DEPPB business processes (including revised process maps), create an implementation plan, obtain appropriate reviews and approvals, and implement the new business processes.

7.2.2.12 Additional Grant Activities

The OIG is working on several other projects intended to improve the efficiency and effectiveness of KASPER. These activities include the following.

- Participating on the IJIS PMP Committee.
- Developing relationships and processes for sharing PMP data with other states.
- Working with the Office of Information Technology to create a Request for Proposal for real-time prescription data collection.
- Supporting development of a prescription drug abuse prevention program for grades 6-12.

Integrated Justice Information Systems Institute

During the National Association of State Controlled Substances Authorities (NASCSA) meeting in October 2005, association leaders requested that based upon the comprehensive scope of the KASPER program, Kentucky provide a representative on the Integrated Justice Information Systems (IJIS) Institute's Prescription Monitoring Program committee. The IJIS PMP committee mission is to develop PMP information exchange specifications to guide the implementation of future systems for exchanging data among states. CHFS has assigned a committee member who is actively participating and supporting the IJIS efforts. The IJIS PMP committee is currently working on a pilot project to share PMP data between the states of California and Nevada. The next phase may include a multi-state data sharing project (i.e.; Kentucky, Indiana, Ohio, West Virginia and Michigan). IJIS is supported by the Bureau of Justice Assistance within the U.S. Department of Justice.

Sharing PMP Data with Other States

In addition to participating on the IJIS PMP committee project noted above, we plan to partner with selected border states that have implemented or are close to implementing their PMPs, to begin planning the processes and systems that will allow us to share PMP data. The IJIS committee effort is focused on developing a technical architecture for PMP data exchange and establishing guidelines for the agreements to be developed by the states. We believe our effort will be complimentary to the IJIS committee project. We plan to utilize the technical framework being established by the IJIS committee, and to provide input and support to the IJIS committee with developing the data sharing guidelines and agreements based upon our work with partner states.

Real-Time Data Collection

The OIG is working with the Office of Information Technology to develop a Request for Proposal (RFP) for real-time prescription data collection. Based upon preliminary discussions with vendors processing prescription drug claims for insurance companies, we believe it may be possible to utilize one of these vendors to capture the majority of Kentucky controlled substance prescriptions during benefit validation at the time the prescription is being dispensed. We would still need to capture data for controlled substance prescriptions not processed by these vendors, but this can be accomplished through existing processes. Capturing a significant amount of prescription data in this manner would constitute a major step toward implementing real-time prescription data collection.

Using Prescription Medications Safely Program

Education and prevention are some of the best weapons we have to combat prescription drug abuse and addiction in youth. The better informed our youth are about the dangers of misused prescription drugs, the better equipped they will be to avoid the potentially disastrous consequences of drug abuse. The OIG is working with a consortium of Kentucky River Community Care, Inc. and the Kentucky Regional Prevention Centers to develop the program *Using Medications Safely: Prevention with the Rx Generation*. Kentucky River Community Care is an eastern Kentucky community mental health center, considered a leader in the field. The Regional Prevention Centers are CHFS agencies that assist individuals and groups to develop prevention programs that will encourage healthy choices about alcohol, tobacco and other drugs. Prevention specialists at each center provide education and training programs, information and consultation services.

Using Medications Safely: Prevention with the Rx Generation is a statewide educational program that will focus on educating youth in grades 6-12 about the dangers of prescription drug abuse and addiction. The program includes a course curriculum and study guide, and an advanced interactive video designed to teach the participant about prescription drugs, their intended uses, and the realistic consequences of improper use. We have entered into discussions with the consortium to provide Hal Rogers Grant funding for development of the program in exchange for identifying KASPER as a program sponsor, and for integrating KASPER into the Using Medications Safely program. This integration involves incorporating KASPER into the course curriculum and study guide, and including KASPER as part of the interactive video story line. To date, we have completed revisions to the course guide to include age appropriate explanations of the concept and function of KASPER, and assisted with development of potential story lines for the interactive video that incorporate a KASPER scene. The *Using Medications Safely: Prevention with the Rx Generation* program is planned for distribution in the fall of 2006.

7.2.3 Hal Rogers Grant Performance Measures

The 2005 Hal Rogers Grant included a series of Performance Measures that are to be reported in accordance with the Government Performance and Results Act (GPRA). Kentucky has made progress in identifying how to capture some of these measures, and providing the results, but there are several measures that we are not yet able to report. Appendix J. Hal Rogers Grant Performance Measures contains a table identifying the performance measures requested by the federal government and the results reported by Kentucky in the 2005 Hal Rogers Grant semi-annual progress report for the period July 1 – December 31, 2005.

7.3 eKASPER System Upgrade (Phase II) Project

In 2004 the Kentucky Legislature appropriated $5,000,000 for the eKASPER System Upgrade (Phase II) Project. The intent of the project is to provide upgrades and enhancements to the eKASPER system. The estimated completion date of the project is March 31, 2008. This funding is in addition to funding provided by the federal government through the Hal Rogers Grants. Staff members from the Office of the Inspector General who support KASPER, work very closely with Office of Information Technology (OIT) personnel who will implement system changes and enhancements to KASPER under the upgrade project. Efforts funded under the Hal Rogers Grants include working with focus groups and other user groups to determine potential improvements to KASPER, assisting OIT to gather user requirements for such improvements, coordinating communications between OIT and the focus and user groups, and assisting with training and communication efforts related to system enhancements. The eKASPER System Upgrade Project funding is being used to implement the technical system changes and enhancements originally planned under the project as well as additional enhancements identified as a result of efforts performed under the Hal Rogers Grants or recommended by the KASPER team and KASPER users.

Project Funding and Costs

The source of funding is the General Fund, and the cost elements specified include the following:

Hardware	$1,090,000
Software	825,000
Professional Services	2,761,000
Other	324,000
Total	$5,000,000

Explanation of Other Costs:

With the reorganization of the cabinet, the agency responsible for KASPER has changed from the Department for Public Health to the Office of the Inspector General. The other costs contained in this project of $324,000 include relocating KASPER staff from their current office space to a larger, more appropriate office space that will improve efficiency and productivity, and increase physical security for the KASPER administration and operation processes.

Explanation of Project Budget:

The project budget is a preliminary in-house estimate based on an analysis of the KASPER Enhancement Project (to develop eKASPER). A project of this size and complexity requires significant research, analysis and planning to accurately pinpoint technology solutions, methodologies, costs and timelines.

Proposed Enhancements to eKASPER

Following is a brief description of the activities and proposed enhancements planned for the eKASPER System Upgrade Project. These activities and enhancements are sequenced in order of their priority as currently established by CHFS.

1. Streamline the business processes for the Drug enforcement and Professional Practices Branch. This effort is discussed in more detail in section 7.2.2.11 Streamline Business Processes. While the actual business process improvement effort is being performed under the Hal Rogers Grant, it is anticipated that some recommendations from the business process improvement project will have system implications for KASPER. Any system changes or enhancements will be implemented as part of the eKASPER System Upgrade Project.

2. Create a Request for Proposal (RFP) to solicit bids from vendors who have the capability to reduce prescription data collection time from thirty (30) days to less then 24 hours for dispensers that have electronic applications. Approximately 98% of dispensers in Kentucky currently use electronic systems to track their prescriptions. For those dispensers that do not have electronic systems, data collection will be within regulatory requirements established by the Commonwealth. CHFS currently contracts with Atlantic Associates to collect prescription data from 2,200 Kentucky pharmacies. There are two main sources of delay on the reporting of pharmacy data: processing time at Atlantic Associates and the frequency with which the data is collected. Mandating more frequent collection of data using the existing process requires modification to regulation 902 KAR 55:110. To help improve the timeliness of collected data, a change to this regulation was filed March 15, 2006 to reduce the required dispenser reporting time from 16 days to 8 days. Collection of data as described in the RFP would not require any further legislation or regulatory action, and would reduce or eliminate both current sources of delay, moving the Commonwealth to a near real-time PMP system for the majority of controlled substance prescription data. Within Kentucky a large percentage of dispensing agencies utilize the services of a data switching companies to verify prescription data before filling the prescription. The majority of dispensing agencies also utilize pharmacy management or

equivalent software that they can use to create an electronic record of this data. It is anticipated that a vendor can collect this information via the data switch or directly from the dispensing agency and submit the data to a KASPER staging server once per day via a batch data transmission process. Data for controlled substance prescriptions not processed by the data switch can be captured through existing processes. Capturing a significant amount of prescription data in this manner would constitute a major step toward implementing real-time prescription data collection. This phased approach to implementing real-time data collection allows for the use of existing systems and technology to provide more timely data without creating mandates that may require massive and costly infrastructure changes affecting both the Commonwealth and all Kentucky dispensers, who are required to report under the threat of criminal penalty.

3. Modify eKASPER to allow judges who administer a drug diversion or probation program to become registered users of the system and obtain KASPER reports, as provided for in KRS 218A.202 (6) (g). These judges are currently using court orders to obtain KASPER reports for their use. Modifying the system to allow them direct access will streamline the process for these judges to obtain KASPER.

4. Modify the system to allow dispensers and the Kentucky Board of Pharmacy to obtain a report that details their controlled substance prescription data transmissions to CHFS based upon a requested date range. This enhancement will eliminate most of the existing cards that are mailed to the dispensers to confirm receipt of their data transmissions. This will provide dispensers a more efficient tool to monitor that they are properly reporting controlled substance prescriptions dispensed as required under KRS 218A.202. It will also provide the Board of Pharmacy with a more efficient method to confirm dispensers are adhering to the statute during the standard inspection process.

5. Enable data validation on critical data elements. Currently there is not a single reliable patient identifier within prescription records. eKASPER provides data quality enhancements, but more needs to be done to enhance the eKASPER reports and to proactively determine prescription drug abuse. Because of the current issues requiring a single patient identifier, OIG is seeking an enhancement to the KASPER program to better validate the social security number and drivers licenses that may be provided at the time a prescription is paid for by the patient or patient representative. These features will also be used to further validate prescriber, dispenser and law enforcement users of the eKASPER system

6. Expand the eKASPER data warehouse and trend reporting capabilities. Legislation enacted in 2004 requires that the OIG provide trend reporting from the KASPER program. While the current database structure and hardware will allow for basic trend reports, new hardware and software may need to be implemented to provide full trend reporting capability. The Cabinet is currently working with the organizations and entities that are allowed access to KASPER trend data as provided for in KRS 218A.240, to determine the types of reports to be created, the appropriate distribution of the reports, and the amount of data mining that will be done on the data stored in the KASPER application. The OIT is also investigating whether there is one solution that can provide both the trend reporting and data warehouse capabilities.

7. Add Web Self-Service Support. With the availability of eKASPER, we are expanding our potential user base of prescribers, dispensers and law enforcement officials in the state of Kentucky. In order to maintain a high level of user satisfaction and contain training and support costs, we are seeking a Web-based support tool that will provide users with an intuitive means to navigate through the eKASPER system. We anticipate that Web Self-Service will also decrease

calls to the eKASPER help desk. Planned enhancements include a Frequently Asked Question's (FAQ) page and a brief online tutorial demonstrating the use of KASPER.

8. Move the physical location of the OIG Drug Enforcement and Professional Practices Branch. The DEPPB office is currently located in a small enclosed office of approximately 1000 square feet. With the administration of the eKASPER system a significant amount of additional square footage is required for electronic equipment and increased investigative staff. This project will provide for a larger DEPPB office, while also addressing physical security requirements to help protect and maintain the confidentiality of KASPER data.

9. Fully integrate eKASPER and the Medicaid Management Information System (MMIS). Both eKASPER and MMIS contain prescription drug information. Currently there is no "connection or bridge" between the two systems. A viable connection would provide a valuable program enforcement tool and could further prevent fraud, waste and abuse of Kentucky's Medicaid dollars. A prototype Medicaid/eKASPER Interface (MeKI) was developed under the Hal Rogers Grant. (Refer to section 7.2.2.6 Develop and Test a Medicaid/eKASPER Interface (MeKI) Prototype.) The Medicaid application is currently being updated and the KASPER development team has provided the prototype results to the Medicaid development team to help them develop, test and implement the interface application.

10. Perform a feasibility study to investigate interface capabilities between eKASPER and e-Prescribing systems. e-Prescribing systems are used to transmit prescription data electronically from the prescriber to the dispenser, to reduce transcription errors and improve customer service. A feasibility study needs to be done regarding the ability to develop interfaces between e-Prescribing systems and eKASPER, to allow for more accurate and timely prescription data capture. e-Prescribing and the implications for KASPER is one of the planned focus areas of the e-Health study to be performed during 2006 under an extension to the 2003 Prescription Drug Monitoring Program grant, by consultants from the University of Louisville School of Public Health and Information Sciences. (Refer to section 7.1 2003 Prescription Drug Monitoring Program Grant.)

11. Fully enable the eKASPER application, architecture and requirements to interface with other states PMP's. The interface will be based on the data elements contained in 902 KAR 55:110. In addition, we plan to utilize the Integrated Justice Information Systems (IJIS) Institute PMP information exchange specifications. Developing interfaces with other state PMPs to allow sharing of data will greatly decrease doctor shopping and improve law enforcement capabilities for investigating prescription drug diversion. (Refer to section 7.2.2.12 Additional Grant Activities for a description of the IJIS PMP committee efforts, and our plans for sharing PMP data with other states.)

7.4 National All Schedules Prescription Electronic Reporting Act of 2005

On Thursday, August 11, 2005, President Bush signed into law H.R. 1132, the "National All Schedules Prescription Electronic Reporting Act of 2005," which requires the Department of Health and Human Services (HHS) to award grants to states to establish or improve programs to electronically monitor dispensing of controlled substances. H.R. 1132 authorizes the appropriation of $25 million in each of fiscal years 2006 and 2007, and $15 million a year for fiscal years 2008 through 2010. Representative Ed Whitfield from Kentucky's 1st Congressional District was a primary sponsor of H.R. 1132.

Currently HHS has not received any Congressional appropriation in support of this program, and this program's exact relationship to the Harold Rogers Prescription Drug Monitoring Program has not yet been

determined. The programs have similar intents but vary in their requirements. The Bureau of Justice Assistance (BJA) reports they have made outreach to HHS to coordinate efforts and share information on current state progress in monitoring prescription activity and information sharing standards and processes developed under the Harold Rogers Program. BJA plans to continue to cooperate and work closely with HHS in the implementation of the Act.

The Office of the Inspector General plans to apply for grants available under H.R. 1132 as soon as funds are appropriated and the grant application process opened. Funding will be used to support our efforts to establish relationships and processes to share PMP data with other states, especially Kentucky border states.

8 Effectiveness of KASPER

Measuring the effectiveness of Prescription Monitoring Programs is a key objective at both the federal and state level. The federal government needs performance measurements that will allow it to assess the Hal Rogers Grant program performance, and assist in future budget allocation decisions. At the state level, Kentucky needs the ability to evaluate the impact of KASPER and to demonstrate results that justify the development and operating costs of the program.

The increased efficiency of PMPs allows the early detection of abuse trends and possible sources of diversion. One indication of the effectiveness of prescription monitoring programs is the prevalence of abuse in states with monitoring programs compared with the prevalence in states without monitoring programs. Studies have found that the five states with the lowest number of OxyContin® prescriptions per capita have long-standing prescription monitoring programs and report no significant diversion problems associated with the drug. Conversely, the five states with the highest number of OxyContin® prescriptions per capita do not have prescription monitoring programs and have reported severe abuse problems.[9]

8.1 Federal PMP Measurement Efforts

The Bureau of Justice Assistance is sponsoring a PMP Performance Measures Focus Group consisting of representatives from several states with PMPs, including Kentucky. The focus group is led by consultants from Carnevale Associates LLC, a strategic policy solutions consulting firm. Their leadership of the focus group is based upon the following approach.

1. Develop a logic model representing the underlying program causal structure.
2. Identify indicator domains corresponding to the underlying logic model.
3. Identify data reporting responsibilities across classes of indicators (measures).

The measurement scheme proposed is consistent with federal reporting requirements required by the Office of Management and Budget (OMB) Program Assessment Rating Tool (PART). PART is a tool used by OMB for assessing federal program performance and assisting in budget allocation decisions.[10] The next steps related to federal measures reporting include incorporating the measures into the grant requirements, developing the data collection system, and research and evaluation design. There is no published completion date for this effort, but the consultants have expressed the desire to begin collecting data as part of the semiannual Hal Rogers Grant progress reporting requirement.

2005 Hal Rogers Grant Performance Measures

In addition to the federal PMP measurement effort described above, the 2005 Hal Rogers Grant contained specific measurements that are to be reported in the semi-annual progress reports. Appendix J. Hal Rogers Grant Performance Measures contains a table identifying the performance measures requested by the federal government and the results reported by Kentucky in the 2005 Hal Rogers Grant semi-annual progress report for the period July 1 – December 31, 2005

[9] U.S. Department of Justice, Bureau of Justice Assistance Web site, Programs; Harold Rogers Prescription Drug Monitoring Program.

[10] Carnevale Associates LLC, *The Program Assessment Rating Tool and the Federal Drug Control Budget*, Information Brief April, 2005.

8.2 Retrospective KASPER Data Analysis

8.2.1 Background

One objective of the 2004 Hal Rogers Grant was to collect and analyze data that can be used as a baseline for comparison to data after the implementation of eKASPER and the educational interventions developed under the grant. The Cabinet for Health and Family Services contracted with the Kentucky Injury Prevention and Research Center (KIPRC) to complete the initial data collection and analysis. KIPRC is nationally recognized as a leading applied injury research center, whose mission is to reduce the rate of injuries and related death and disability.

KIPRC was tasked with analyzing correlations between defined outcome indicators and the levels of prescription activity with particular emphasis on geographic variables. The primary purposes of the study were:

1. To summarize demographic and geographic trends in prescriptions reported to KASPER from 2000-2002;
2. To summarize demographic and geographic trends in the leading causes of death and hospitalization due to injuries among Kentucky residents; and
3. To identify geographic associations between the volume of prescriptions filled and the incidence of injury.

Reducing the adverse effects of pharmaceutical controlled substance abuse – particularly fatal and non-fatal drug overdoses - is a core objective of Kentucky's Prescription Monitoring Program. In addition, research literature suggests there are other potential adverse effects associated with prescription drug use, most notably falls by the elderly and motor vehicle crashes.

8.2.2 Methodologies

Three data sources were used for the analysis:

1. For prescriptions: KASPER system prescription databases from 2000 – 2002.
2. For fatalities: National Center for Health Statistics (NCHS) multiple-cause-of-death (MCOD) public use data files from 1999-2002.
3. For hospitalizations: Kentucky COMPdata hospital discharge data (HDD) files from 2000 – 2002.

File Preparation

In order to avoid multiple counting of cases, the MCOD, HDD and KASPER files were examined for duplicate records, and when identified duplicate records were dropped.

KASPER variables used in the analysis included the recipient's date of birth, gender, and resident zip code; National Drug Control (NDC) number; and the metric quantity prescribed. KIPRC ran frequencies of each variable to assess the extent of invalid and missing values. Year of birth was used to calculate the recipient's age by subtraction from the year in which the prescription was filled. This resulted in some negative ages as well as some ages with unlikely or impossibly high values. Age 114 was defined as the maximum reasonable for purposes of the analysis. Ages less than zero or greater than 114 were considered missing. Zip codes were mapped to county codes using tables obtained from the U.S. Postal Service. County was then used to create variables for Area Development District (ADD) and level of urbanization. Prescriptions were grouped into therapeutic classes as defined by a drug table provided with the KASPER database. The therapeutic classes were further condensed to create the broad groupings used in this report: narcotic analgesics (NA) benzodiazepines (BZ), stimulants (ST) and sedative-hypnotics (SD). Results were reported

for both the number of prescriptions and the metric quantity of drug prescribed. Metric quantities as high as 90,000 were identified in the KASPER database. Ten thousand was identified as the highest reasonable value for metric quantity so prescription records having values higher than 10,000 were dropped from this analysis.

The mechanism of injury (drug overdose, motor vehicle traffic crash, fall, adverse effects of medication) was determined using the underlying cause of death field on the MCOD files and the external-cause-of-injury field on the HDD files. Drug involvement in fatalities was determined by searching the supplemental cause of death fields on the MCOD files for ICD-10 T-codes in the range T36-T50 ('Poisoning by drugs, medicaments and biological substances'). Drug involvement in hospitalizations was determined by searching the nine diagnosis fields for ICD-9 N-codes in the range 960-979 (also 'Poisoning by drugs, medicaments and biological substances').

Outcome Indicators

Seven injury outcome indicators were created – four primary and three ancillary – describing the incidence of various kinds of injuries among Kentuckians.

Primary injury outcome indicators

1. Fatal unintentional drug overdoses (UDOF)
2. Fatal intentional drug overdoses (IDOF)
3. Hospitalizations for unintentional drug overdose (UDOH)
4. Hospitalizations for intentional drug overdose (IDOH)

Ancillary injury outcome indicators

Fatal motor vehicle traffic crashes (MVCF)
Hospitalizations for motor vehicle crashes involvement (MVCH)
Hospitalizations for unintentional falls (UFH)

8.2.3 Results

Complete details of the study are contained in the report "Prescription Drugs and Injuries in Kentucky: An Analysis of Prescriptions Reported to the Kentucky All-Schedule Prescription Electronic Reporting System (KASPER) from 2000-2002". Key results from this study are:

1. Narcotic analgesics (NA) and benzodiazepines (BZ) were the most commonly prescribed scheduled drugs reported to KASPER for 2000-2002, comprising 76% of all reported prescriptions.
2. Slightly more than half of reported prescriptions were for NA, and one-quarter were for BZ.
3. NA and BZ were also the leading drugs mentioned on hospital discharge records for Kentucky residents who were hospitalized for drug overdoses from 2000-2002.
    a. Psychotropic drugs in general accounted for 31% of substances mentioned on hospital discharge records for *unintentional* drug overdoses from 2000-2002, BZ-based tranquilizers in particular were 17% (antidepressants were another 6.6%).
    b. Analgesics, antipyretics, and anti-rheumatic drugs in general represented another 24% of substances mentioned on hospital discharge records for *unintentional* drug overdoses from 2000-2002, in particular, 'opiates and other related narcotics' were 14%.
    c. Psychotropic drugs in general accounted for close to half (46.5%) of substances mentioned on hospital discharge records for *intentional* drug overdoses from 2000-2002, in particular, BZ-based tranquilizers were 21% (antidepressants were another 17%).

    d. Analgesics, antipyretics, and anti-rheumatic drugs in general represented another 23% of substances mentioned on hospital discharge records for *intentional* drug overdoses from 2000-2002, in particular, 'opiates and other related narcotics' were about 6%.
4. Information about specific drug involvement in fatal overdoses is limited, since in the majority of cases the substances are reported only as 'other and unspecified' on the computerized death records. It would be worthwhile to determine whether improvements are possible in the toxicology data collection process in fatal overdose cases.
5. Fatal unintentional drug overdoses among Kentucky residents more than doubled from 1999 (148 cases) to 2002 (348 cases). This mirrors a broad, national trend that has emerged within the past eight to ten years.
6. Motor vehicle traffic crash (MVTC) deaths for Kentucky residents increased steadily from 718 in 1999 to 821 in 2002.
7. There were 22,421 persons aged 65 or older hospitalized for falls from 2000 to 2002.
8. Research literature indicates that BZ's increase the risk of falls in the elderly and motor vehicle traffic crash involvement for drivers of all ages. Most of the studies we reviewed found no significant impairment in driving ability for persons using NA.
9. Preliminary investigations of correlations between NA and BZ and injuries in Kentucky were largely inconclusive. More extensive study is needed in this area.
10. NA's get a great deal of attention due to their potential for diversion and their involvement in fatal overdoses. It appears that BZ and other psychotropic agents, while less commonly prescribed than NA, should also be considered a high priority in terms of their potential for adverse effects on the health and safety of Kentuckians. Specifically, their role in intentional and unintentional drug overdoses (nonfatal as well as fatal), motor vehicle traffic crashes, and falls in the elderly should be more closely examined.

8.2.4 Conclusions

Prescriptions

More than half of the prescriptions reported to KASPER from 2000 to 2002 were Narcotic Analgesics (NA), and more than 75% were Narcotic Analgesics or Benzodiazepines (BZ). The research literature over the past fifteen years has consistently found correlations between these classes of drugs and various kinds of injuries, particularly motor vehicle traffic crashes and falls. For these reasons, it seems worthwhile to explore the extent to which NA and BZ contribute to injuries among Kentuckians.

Injuries

Motor vehicle traffic crashes (MVTC's) and unintentional drug overdoses are among the leading causes of injury-related death for Kentuckians, and have been rising in recent years – as has the number of prescriptions of both NA and BZ. Falls, MVTC's, and drug overdoses (both intentional and unintentional) are among the leading causes of injury-related hospitalizations in the Commonwealth. There are many circumstances that contribute to these types of injuries, but one shared commonality is they have been linked to the use – legitimate or otherwise – of prescription drugs, especially NA and BZ.

Correlations Between Prescription Drugs and Injuries

Unfortunately, the time available for analyzing the data for correlations was very limited. Given this constraint, the approach was to look for simple correlations between the volume of drugs (represented by prescription rates) and the incidence of injury (represented by rates of death and hospitalization) by ADD. This limited analysis established few clear connections with one exception: the prescription rate for NA and the rate of unintentional fatal drug overdoses demonstrated a strong association.

In conclusion, this study effectively demonstrated use of the data sources (KASPER, NCHS MCOD, and COMPdata HDD), and established baseline data from which to analyze and track changes over time. However the analysis of correlations was very limited. Further studies may be able to analyze correlations at a greater level of depth, including more detailed analysis of geographic areas.

8.3 2004 KASPER Satisfaction Survey

8.3.1 Background

KASPER has experienced many enhancements since its development in 1999. It was designed to be a source of information for practitioners and pharmacists and as an investigative tool for law enforcement. Requests for reports have continued to grow from 3,105 requests processed in the first six months to 122,469 requests in 2004. In October 2004 a survey was launched to gather the opinions of the KASPER user community to assess user satisfaction and to evaluate the usefulness, effectiveness and efficiency of KASPER as a tool for practitioners, pharmacists and law enforcement personnel in the fight to prevent the diversion of prescription medications. Survey implementation was concluded in June 2005. Results from the survey are being used to create recommendations for enhancements to the KASPER system and for the development of educational materials to address the needs of the user community.

As part of the current Hal Rogers Grants, a new 2006 KASPER Satisfaction Survey is being planned to determine user satisfaction with the eKASPER system. The survey booklet has been developed and should be mailed to eKASPER users early in the second quarter of 2006.

8.3.2 Methodologies

The 2004 KASPER Satisfaction Survey was designed to address grant objectives. Questions were developed using a key-person interview method to include the eKASPER project manager, program staff, law enforcement personnel, and members of the licensure boards. Survey question construction and format strictly followed the Dillman *Tailored Design Methodology* (Dillman, 1978; 2000). To ensure representation, a stratified random sampling method was employed. The state was divided into six investigative regions. Provider and Requester sample frames were developed. From these sample frames a random sample was drawn and stratified by investigative region. A 95 percent confidence interval was selected with a 5 percent sampling error. An accommodation in sample size was made to ensure a 50/50 split in response variation. From each stratified sample, a systematic sample was then selected and the final survey sample was selected. Survey implementation followed an 8-week sequence from initial mail out to follow up to final mailing.

8.3.3 Results

The 2004 KASPER Satisfaction Survey was intended to establish baseline data regarding the use, effectiveness, efficiency, and demographics of KASPER. Although the survey produced an overall 63.2% response rate for both Provider and Requester respondent groups, only the Requester respondent group responses (n = 434) were used for this descriptive analysis, as we were initially interested in respondent comments from those who actually requested KASPER reports in the period assessed. A 67.7% response rate was achieved among Requester respondents. Complete results of the survey are included in the report KASPER Satisfaction Survey Results, available from the Office of the Inspector General. Following are the results of a key subset of survey questions providing an initial point of reference regarding the survey respondents' view of KASPER. All data is based on the 434 Requestor survey responses.

KASPER Use

Question A1: “Do you use KASPER to request patient reports?”
Response: 85.5% responded “Yes”, 9.2% responded “No” and 5.3% did not respond.

KASPER Effectiveness

Question A2: “In general, to what extent are you satisfied or dissatisfied with the KASPER reporting system?”

Response: 80.9% responded “Very Satisfied” or “Somewhat Satisfied”, 6.2% responded “Neutral”, Somewhat Dissatisfied” or “Very Dissatisfied”, and 12.9% did not respond.

Question A3: “Effectiveness is often defined as producing a desired result. To what extent do you feel KASPER is an effective patient management tool to keep track of your patients’ scheduled prescription drug history?”

Response: 83.4% responded “Very Effective” or “Somewhat Effective”, 3.5% responded “Neutral”, Somewhat Ineffective” or “Very Ineffective”, and 13.1% did not respond.

Question B1: “Based on your experience with the KASPER system, how much do you agree or disagree with the following statement? ‘KASPER is an excellent tool for identifying potential “doctor shoppers” – patients who visit multiple doctors to get prescriptions for narcotics.”

Response: 86.2% responded “Strongly Agree” or “Somewhat Agree”, 1.6% responded “Neutral”, Somewhat Disagree” or “Strongly Disagree”, and 12.2% did not respond.

Question B4: “In general, to what degree do you find KASPER patient reports to be accurate or inaccurate?”

Response: 84.3% responded “Very Accurate” or “Somewhat Accurate”, 3.5% responded “Neutral”, Somewhat Inaccurate” or “Very Inaccurate”, and 12.2% did not respond.

Question B5: “In your opinion, do you believe the data from KASPER patient reports reflects the patient’s scheduled drug use?”

Response: 75.1% responded “Yes, Always” or “Yes, Usually”, 12.0% responded “Sometimes”, “Seldom”, “Almost Never”, or “Never”, and 12.9% responded “No Opinion” or did not respond.

Question B6: “Do you think that all retail pharmacies are reporting all scheduled drugs they dispense?”

Response: 21.0% responded “Yes”, 17.7% responded “No”, 49.5% responded “Don’t Know” and 11.8% did not respond.

Question B7: “Do you believe that the drug listed on a specific patient report belongs to that patient and only that patient?”

Response: 47.7% responded “Yes”, 14.3% responded “No”, 26.0% responded “Don’t Know” and 12.0% did not respond.

Question C4: “When treating a patient, how important is a KASPER patient report in helping you make your decision about which drug to prescribe?”

Response: 63.4% responded “Very Important” or “Somewhat Important”, 11.9% responded “Neutral”, Somewhat Unimportant” or “Not Important”, and 24.7% did not respond.

KASPER Efficiency

Question A4: “Efficiency is defined as the ability to produce a desired result with a minimum of effort. To what extent do you feel KASPER is an efficient or easy to use patient management tool to keep track of your patients’ prescription drug history?”

Response: 78.4% responded “Very Efficient” or “Somewhat Efficient”, 8.0% responded “Neutral”, Somewhat Inefficient” or “Very Inefficient”, and 13.6% did not respond.

Question C15: “Are KASPER reports easy to understand?”

Response: 80.6% responded “Yes”, 2.3% responded “No”, and 17.1% did not respond.

Question C16: “Do you feel that you require user training to make better use of the KASPER reporting system?”

Response: 7.4% responded “Yes”, 67.3% responded “No”, 16.1% responded “Not Sure” and 9.2% did not respond.

KASPER Demographics

Question D12: “Would you consider your practice to be located in an urban or rural area?”

Response: 46.8% responded “Urban”, 34.8% responded “Rural”, 3.7% responded “Not Sure”, and 14.7 % did not respond.

8.3.4 Conclusions

Based upon initial review of the survey data, we feel KASPER has been accepted by health care professionals as a legitimate tool to assist them with patient prescription drug treatment. Our initial conclusions as they relate to our baseline data categories follow.

KASPER Use

The survey indicated a high level of usage by respondents; however we know that a significant number of physicians and pharmacists are not yet using KASPER. We believe the survey results indicate that once a health care practitioner becomes aware of KASPER, they may realize the usefulness of the system and begin to request reports for their patients when appropriate. This reinforces one of our grant objectives, which is to publicize KASPER to increase the visibility of the system throughout the health care community, and to increase the number of health care practitioners who use the system.

KASPER Effectiveness

Survey results indicate that KASPER users tend to believe the system is an effective tool to assist in treatment, however there appear to be concerns about the quality (and possibly the timeliness) of the data. Our plans are to address these are concerns using the coordinated efforts are resources from the Hal Rogers Grant team, and the Office of Information Technology (under the eKASPER capital project).

KASPER Efficiency

Initial analysis would indicate that the KASPER system and KASPER reports are relatively easy to use and require minimal training. However, it appears that we need to improve the overall efficiency of the system. Now that eKASPER has been implemented, we hope to increase the number of practitioners using the Web-based system. This should help improve the overall efficiency ratings for the system.

KASPER Demographics

The survey yielded a great deal of demographic data, but we have not yet been able to conduct an in-depth analysis of that data. One concern was whether we would receive responses from both urban and rural practitioners. It appears that the survey results do represent a cross section of rural as well as urban practitioners. Our plans are to utilize the survey data along with KASPER trend reports to determine potential problems or trends in geographic regions of the state that may help us understand where we need to place more emphasis on KASPER usage and in addressing prescription drug abuse and diversion problems.

9 KASPER Education and Training

A key objective of the Office of the Inspector General is to increase awareness and understanding about the KASPER program throughout the state, in order to make the most effective use of the program and the information available in the system. This includes providing information and training about KASPER to existing and potential users of the system, as well as providing information to attorneys, judges, civic organizations and the general public about the program and how it helps to address prescription drug abuse and diversion in Kentucky.

KRS 218A.202 includes a statutory mandate for the Cabinet for Health and Family Services to work with each board responsible for the licensure, regulation or discipline of practitioners, pharmacists, or other persons who are authorized to prescribe, administer, or dispense controlled substances, for the development of a continuing education program about the purposes and uses of KASPER. In addition, the statute calls for CHFS to work with the Kentucky Bar Association and the Justice Cabinet for the development of continuing education programs for attorneys and for law enforcement officers about the purposes and uses of KASPER.

Under the Hal Rogers Grant programs, the OIG has undertaken an extensive effort to develop educational and training presentations and supporting materials, to meet the statutory education requirements noted above and to implement the education-based recommendations made by the Hal Rogers Grant focus and working groups. OIG team members utilize these materials to participate in meetings, trade shows and events to provide information about the KASPER program and to encourage health care professionals and law enforcement officials to register to use KASPER. In addition, the OIG team members participate in meetings and sessions with schools, civic associations, judicial organizations and legal organizations, to provide information about the background and development of KASPER, who may use the system, what information is contained in KASPER reports and how the reports may be used, as well as how to identify when someone may have a prescription drug abuse or addiction problem, and how they can obtain help. Appendix H. KASPER Event Schedule contains a list of recent events, presentations and training sessions with participation by OIG team members.

9.1 Education and Training Materials

Under the Hal Rogers Grant, the OIG has developed a portfolio of KASPER materials to assist with education, training, and awareness activities.

Trade Show Exhibit Booth

In order to reach the broadest audience of professionals who should utilize KASPER and/or be aware of the KASPER program, the OIG has developed a KASPER Exhibit for use at various meetings and trade shows that is customized based upon the target audience. The exhibit includes a KASPER banner, a display showing the Web pages that are accessed to register for a KASPER userid and to request KASPER reports, and a laptop computer that displays a repeating video testimonial about KASPER by a professional appropriate to the trade show audience (physician, pharmacist or law enforcement). In addition, the exhibit stocks KASPER brochures specific to the audience, and KASPER pens that are available free to attendees. The KASPER exhibit has received very favorable responses from conference and trade show participants. We intend to continue to improve the display materials and increase the number of trade shows and conferences in which we participate, in order to increase the awareness and usage of KASPER by authorized professionals.

Brochures and Pens

The OIG has developed the following brochures and pens that are made available during presentations, conferences, trade shows, meetings and other events.

1. Health Care Provider Brochure. This brochure is targeted toward physicians, dentists, pharmacists and nurses, to provide them with information about how to access KASPER, who may request a report, the information contained in a KASPER report, how the information may be used by health care professionals, doctor shopper behaviors, and resources for help in intervention. While a nurse currently may not obtain a master account under KASPER, many nurses become delegates under a physicians master account, so we want to ensure they understand the intent and restrictions on KASPER reports as well.
2. Law Enforcement Brochure. This brochure is targeted toward law enforcement officials to provide them with information about how to access KASPER, who may request a report, the information contained in a KASPER report, how the information may be used by law enforcement, doctor shopper behaviors, diverting provider behaviors, and resources and contacts for assistance with investigations.
3. Attorney Brochure. This brochure is targeted toward judges, attorneys, and other legal professionals to provide them with background information on the KASPER program, who may request a report, the information contained in a KASPER report, how the information may be used, the information safeguards and security on KASPER data, and contacts for more information.
4. Public Brochure. This brochure is targeted toward the public to provide them with information about prescription drug abuse and addiction, warning signs and tests for prescription drug abuse, what individuals can do to prevent prescription drug abuse, resources and organizations where they can obtain help, and general information about the KASPER program and reports.
5. KASPER Pens. The KASPER pens contain the KASPER logo and access request Web page. They provide an excellent reminder for health care professionals and law enforcement officials to register to use KASPER after a meeting or trade show. In addition, the pens serve as an enticement to the public and other audiences to stop by our KASPER exhibit so we can discuss KASPER and prevention of prescription drug abuse and diversion.

Presentations

The OIG maintains a catalog of KASPER presentations oriented toward each of the appropriate audiences (prescribers, dispensers, law enforcement, legal professionals, and public groups. These presentations are often customized for a specific audience. In addition, we work to constantly review and update the presentations to ensure the information is current and relevant.

Information Packet

Because of the interest shown in KASPER by other states, and the number of states that have requested site visits to review and discuss how Kentucky has implemented our PMP, we have developed a standard information packet for visiting representatives from other states. The information packets contain a copy of the KASPER presentation, the Kentucky statutes and regulations governing KASPER, information about account access and report requests, and other pertinent documentation regarding implementation and operation of the system.

Prescription Drug Quiz Wheel

When presenting KASPER to public audiences who typically do not have any knowledge of KASPER, we utilize a prescription drug quiz wheel as a draw to attract attention to the KASPER exhibit. The quiz wheel contains questions regarding use and abuse of prescription drugs, and is very effective in generating interest and initiating discussions with the public. The quiz wheel was used to great effect at the Kentucky State Fair, where KASPER was the Cabinet for Health and Family Services featured exhibit on August 22, 2005.

We estimate contact was made with over 1,000 fair participants. In several cases, OIG staff members were approached by people who had friends or family members they were concerned about, but they did not know how to identify a prescription drug abuse or addiction problem, or where to obtain help. OIG staff members were able to provide these people with information and advice regarding warning signs and sources for assistance.

9.2 Continuing Education for Health Care Professionals

One of the recommendations made by the Hal Rogers Grant Education Working Group was to develop training for health care professionals on conducting brief interventions. As a result, the OIG has developed a training session covering the following topics.

- KASPER Background
- Problems with Controlled Substances
- Provider Shopping
- The KASPER Program
- Using Enhanced KASPER (eKASPER)
- Intervention – Breaking the Cycle

The intervention component of the training was developed with the guidance and support of the following health care professionals with a wealth of knowledge and experience in the area of prescription drug abuse and treatment:

- Brian Fingerson, R.Ph., Executive Director, Kentucky Professionals Recovery Network (KYPRN),
- Patrick Sammon, Ph.D., Associate Professor Emeritus, Dental and Medical Schools, University of Kentucky,
- Paula S. Schenk, MPH, RN, Program Director, Kentucky Alternative Recovery Network (KARE) for Nurses.

This training has now been conducted with three pilot groups, and has received extremely favorable reviews. We have incorporated course revisions based on feedback from the pilot groups into our current version of the training. The OIG is now working with the University of Kentucky and the University of Louisville to implement this training session as a Web-based course that will be offered on the Continuing Medical Education Web sites of both universities. The class will be available to all health care professionals, who upon successful completion of the course will be eligible for 1 hour of Continuing Education credit. Plans are to have the course available on the Continuing Medical Education Web sites of both universities early in the second quarter of 2006.

9.3 Continuing Education for Law Enforcement Officials

Under Kentucky statutes, KASPER is available to certified peace officers who are engaged in a bona fide specific drug investigation. The OIG has conducted numerous training sessions for law enforcement groups and agencies, but we have still only reached a small percentage of law enforcement officials. We are striving to make all law enforcement officials aware of the value of KASPER in investigating prescription drug abuse and diversion cases, and to increase their usage of KASPER. OIG has contacted the Kentucky Department of Criminal Justice Training (DOCJT) to discuss the possibility of developing Web-based training for law enforcement officials that would provide Continuing Education credit upon successful completion of the training. The DOCJT is a nationally recognized agency that provides state-of-the-art training to law enforcement officers in Kentucky. It is one of four departments in the Kentucky Justice and Public Safety Cabinet. Web-based training developed and implemented by OIG and DOCJT would be a major step in increasing law enforcement awareness and usage of KASPER.

10 A National Perspective on KASPER

Kentucky has implemented one of the most comprehensive Prescription Monitoring Programs (PMP) in the United States. In February, President Bush released a national drug control strategy that hails KASPER as being one of the Nation's flagship PMPs. Kentucky is currently one of only 4 states that track Schedule II – V controlled substances. None of the other states currently provide PMP access to as broad a range of users, for such a wide range of purposes. Kentucky provides access to KASPER patient reports to authorized entities including:

- Prescribers for medical treatment, and dispensers for pharmaceutical treatment for a current patient,
- Law enforcement officers for a bona fide drug related investigation,
- Licensure boards for an investigation of a licensee,
- Medicaid for utilization review on a recipient,
- Grand jury by subpoena, and
- Court order by a judge of competent jurisdiction.

Kentucky is unique in being the only state that provides statutory authority for the Medicaid program to utilize data from the Prescription Monitoring Program, and in assigning ownership of the PMP to the Office of the Inspector General within the Cabinet for Health and Family Services, which has responsibility for investigating Medicaid fraud and abuse. The establishment of this relationship provides an extremely valuable and effective tool for reducing Medicaid fraud and abuse related to controlled prescription drugs.

Kentucky regularly hosts delegations from other states to demonstrate KASPER and discuss the implementation of the system and the results achieved. Several states have requested copies of the Kentucky statutes and regulations controlling KASPER (KRS 218A.202, KRS 218A.240, and 902 KAR 55:110) to use for reference and as models for promulgating their legislation to establish and operate a PMP. In addition, some states have requested the results of the 2004 KASPER Satisfaction Survey to review with their PMP authorities to help understand user perspectives, concerns and satisfaction levels with an existing PMP. This information is useful for helping to obtain regulatory and legislative support for plans to implement or enhance their PMPs.

The KASPER system was a major consideration by federal legislators during development of H.R. 1132, signed into law by President Bush on August 11, 2005. H.R. 1132 implements a grant program to provide for the establishment of a controlled substance monitoring program in each state, and is titled the "National All Schedules Prescription Electronic Reporting Act of 2005" (NASPER). The grants to be made available under this program are to be used to implement PMPs in states that currently do not have a program, and to foster sharing of PMP data among the states.

Kentucky maintains membership in several national organizations focused on controlled substance regulation and law enforcement activities and/or PMP programs. In addition to participating in meetings and conferences conducted by these organizations, representatives from Kentucky are often asked to speak or present KASPER at these meetings. Refer to Appendix G. Organizations Associated with Prescription Monitoring Programs for a description of these organizations.

During 2006, Kentucky will be hosting the National Association of Surveillance and Utilization Review Officials (NASO) at their national conference August 20-23 in Lexington, KY. NASO is the national association for Medicaid Program Integrity Units. KASPER will be the topic of one of the major breakout sessions at the conference. In addition, Kentucky will be represented at the 2006 National Conference of State Prescription Monitoring Programs (sponsored by the National Association for Model State Drug Laws (NAMSDL) April 12-13 in Washington, DC. A KASPER representative will participate in a panel

presentation with representatives from three other state PMPs, to discuss PMP enhancements made possible through the Hal Rogers Grants.

Through early deployment of the KASPER system, implementation of the Web-based system in 2005, continuous improvements to the system, and extensive education and training efforts, Kentucky has earned the reputation as a leader in PMP implementation and utilization. The state plans to continue its leadership role by providing support in the following areas.

- Continuing to provide information and support to other states to help them implement and enhance their PMPs.
- Helping to establish standards for definitions and measurements related to prescription drug abuse and diversion, and for measuring the impact of PMP implementation and enhancements.
- Supporting initiatives to foster sharing of PMP data among states, such as the Integrated Justice Information Systems PMP Committee, and by working with neighboring states to investigate how we can work together to share data.
- Participating on a NAMSDL sponsored PMP Education Working Group to help determine what education tools are needed at different stages of the planning, implementation, or enhancement process for PMPs.

11 Future Plans and Considerations

KASPER has progressed from a basic fax and paper based prescription reporting system when launched in 1998 to a state of the art Web-based Prescription Monitoring Program considered one of leading programs in the nation. Throughout the life cycle of KASPER, the first and foremost priority has been to fulfill the legislative mandates specified by the Kentucky legislature regarding the implementation and operation of Kentucky's PMP. These legislative mandates have provided guidance for the development of the original KASPER system, making KASPER reports available to prescribers and dispensers for patient treatment, and to law enforcement for investigative purposes, development and implementation of training curriculums and programs to educate all groups affected by KASPER, and development of trend reporting capabilities to allow for proactive health care and law enforcement initiatives.

While KASPER has become an indispensable tool for health care and law enforcement in the fight against prescription drug abuse/addiction and diversion, the severity of the prescription drug problem requires that KASPER be enhanced and improved on an ongoing basis. The Kentucky legislature has addressed the need for continuous improvement by allocating $5 million in funding for the eKASPER System Upgrade Project to run through 2008. This funding will provide the CHFS Office of Information Technology with the funding needed to implement technical system changes and enhancements. The Office of the Inspector General is supporting continuous improvement of KASPER by providing the Drug Enforcement and Professional Practices Branch the tools and support needed to administer KASPER and conduct drug related investigations, and by utilizing the Hal Rogers Grant program to support ongoing KASPER education and training efforts, and to help guide identification and implementation of improvements and enhancements to KASPER.

This section describes some of the key initiatives planned or under consideration to enhance the efficiency and effectiveness of KASPER. Priorities for implementing these planned enhancements and initiatives are established based upon feedback from KASPER users and focus groups in order to meet the needs of the KASPER user community.

11.1 KASPER and e-Health

"e-Health" can be defined as the use of information technology to improve the delivery of health care. This new development in the health care field holds the potential to revolutionize the way patients, physicians, pharmacists and other health professionals interact. Through broader adoption of more advanced health information technology, the health care system can reduce medical errors by allowing physicians access to complete medical histories, improve patient privacy, limit transactional fees and overhead costs associated with record-keeping and administration, and empower patients to play a more active role in their own health. In addition, e-Health systems have great potential to improve efforts to prevent prescription drug abuse and diversion. KASPER will clearly have an important role to play in development of an e-Health (electronic health information) system in Kentucky.

In 2005, as a result of collaboration by the Governor, a bipartisan group of legislators and CHFS, Governor Fletcher signed into law SB 2, which created the Kentucky e-Health Network and the Kentucky e-Health Network Board which is charged with its development and oversight. The responsibility of the e-Health Network Board is to implement and oversee the operation of an electronic health network in the Commonwealth.

As discussed in section 7.1.1KASPER and e-Health Study, the Commonwealth Office of Technology is in the process of implementing a Memorandum of Agreement authorizing the University of Louisville School

of Public Health and Information Sciences to perform a study of e-Health systems and their implications for KASPER. It is anticipated the study will focus on identifying the issues and advantages of integrating KASPER into an e-Health system, and will identify security and privacy issues that may raised as a result of this type of integration. Results of this study may help guide future development and enhancement plans for KASPER. The study is scheduled for completion by December 31, 2006.

11.2 Implement a Medicaid/eKASPER Interface

As discussed in section 4.7 KASPER Usage by Medicaid, Medicaid spending has become an issue of major concern at both the state and federal level, and state governments must constantly seek ways to reign in Medicaid spending on health care, while continuing to provide necessary medical care to those in need. The Division of Fraud, Waste and Abuse Identification and Prevention is responsible for efforts to identify and prevent abuse and/or misuse in the Medicaid program, including fraud related to abuse and diversion of controlled substance prescriptions.

The Department for Medicaid Services may use KASPER data and reports for the purpose of identifying Medicaid recipients whose usage of controlled substances may be appropriately managed by a single outpatient pharmacy or primary care physician, and may share the data or reports regarding overutilization by Medicaid recipients with an authorized regulatory board or with an authorized law enforcement officer. This provides the Department for Medicaid Services the ability to be more efficient and proactive in detecting and addressing situations of prescription drug abuse or diversion by Medicaid recipients.

Under the current process members of the Programs Enforcement Branch within DFWAIP receive a report from the Medicaid system identifying a list of 1,000 potential abusers. The specialists request a claim detail report and a KASPER report, if necessary, on a selection of these users in order to identify potential abusers. Reports from both systems must be reviewed because some Medicaid recipients may pay for controlled substance prescriptions in cash, to avoid a Medicaid claim record. KASPER is able to track all prescriptions regardless of method of payment. When possible abuse is identified, a rationale is written for Lock-in referrals (limiting the Medicaid recipient to one prescriber and dispenser); or if criminal activity is suspected the recipient's information is forwarded to OIG Special Investigations for further research.

Under the Hal Rogers Grant, a Medicaid/eKASPER Interface (MeKI) prototype was developed as a proof of concept for an interface to automate many of the manual investigation activities currently performed by the Office of the Inspector General Programs Enforcement personnel. Refer to section 7.2.2.6 Develop and Test a Medicaid/eKASPER Interface (MeKI) Prototype for more information about the results of the prototype. A new Web-based Medicaid system called Interchange is now under development, with a planned implementation data of November 2006. Interchange will interface with the Medicaid Pharmacy Benefit Management (PBM) system and KASPER. The PBM system will utilize a weighting system developed as part of the MeKI prototype that analyzes patterns identified as belonging to abusers and fraud perpetrators, to identify the top 200 (or other established threshold) potential abusers. KASPER data will automatically be extracted for those potential abusers, and Interchange will create a report that will provide the combined data in a clear, consistent report that can be used by Programs Enforcement personnel to investigate the recipients. Implementation of the MeKI prototype and the KASPER interface will be completed as part of the Interchange development project, and the eKASPER System Upgrade project.

11.3 2006 KASPER Satisfaction Survey

The 2004 KASPER Satisfaction Survey provided an excellent vehicle for assessing user satisfaction with the paper and fax based KASPER system. Refer to section 8.3 2004 KASPER Satisfaction Survey for more

information regarding that survey and the results. With eKASPER having now been in operation for over one year, it is important to survey users to determine their satisfaction with the Web-based system, and to identify users' suggestions for improving the system. A 2006 KASPER Satisfaction Survey Booklet has been created that includes sections on user satisfaction, user beliefs and opinions, user business practices, general user characteristics, along with sections designed specifically for law enforcement, prescribers and dispensers. The survey booklet is introduced by a letter of support from United States Representative Harold "Hal" Rogers from Kentucky's 5th Congressional District.

The 2006 KASPER Satisfaction Survey question construction and format follow the Dillman *Tailored Design Methodology* (Dillman, 1978; 2000). The KASPER project epidemiologist utilizes a stratified random sampling method with a 95 percent confidence interval selected, with a 5 percent sampling error. Survey implementation will follow an 8-week sequence from initial mail out to follow up to final mailing. Plans are for the survey booklets to be mailed to the random sampling of users beginning in May 2006. A summary of survey results will be made available to interested parties on the KASPER Web site.

The 2006 KASPER Satisfaction Survey will provide the opportunity to obtain pertinent information about how users view KASPER, their usage of the system, their satisfaction with the system, and their recommendations for improving the system, as well as providing valuable demographic information about the system users. This information will be utilized to identify where resources should be focused for modifications and enhancements to the system and for additional education and training. Plans are to begin distribution of the survey in May 2006.

11.4 KASPER Web Site

A Web site has been developed to provide information about the KASPER program and related topics, to health care professionals, law enforcement officials and the general public. The Web site address is www.chfs.ky.gov/KASPER. The Web site currently contains general information about KASPER, information regarding how to recognize a prescription drug abuse or addiction problem and how to obtain help, information about how to obtain a KASPER account, and links to the Web sites of related organizations and support resources.

Plans include expanding the Web site to include copies of KASPER presentations and other reference materials, adding additional Web site links to related sites and organizations, adding a set of KASPER frequently asked questions, including copies and/or links to KASPER related news articles and other items of interest, communicating planned system enhancements, and publishing the KASPER trend data GIS maps on a quarterly basis. The intent is for the KASPER Web site to become the focal point and primary source for information about the KASPER program, accessible to any interested parties.

11.5 Sharing PMP Data with Other States

During the 2004 KASPER Satisfaction Survey, when asked what is the best way to reduce prescription drug diversion many responders commented that they need KASPER to include prescriptions from other states, or that there should be a national PMP developed to provide that data. Based upon the success of PMPs within the states that have implemented the programs, and the need to expand the data available to health care professionals and law enforcement to include patient and dispenser data from all sources, not just within a particular state, the federal government, through the Bureau of Justice Assistance (BJA) is sponsoring and funding a PMP Committee, organized and managed by the Integrated Justice Information Systems (IJIS) Institute. Kentucky is represented along with seven other states on the IJIS PMP Committee. The IJIS PMP Committee is currently supporting a pilot project to demonstrate the exchange of PMP data between

California and Nevada. The IJIS effort is related to developing the technical guidelines and formats for PMP data sharing utilizing the Global Justice XML Data Model (GJXDM), a technical model for data exchange. The pilot project will also include development of a generic Memorandum of Understanding to provide a model agreement for establishing the rules by which states will agree to share data including authorized recipients, allowable use of the data, etc. IJIS is also considering establishing two regional pilot projects, potentially one in the northeast and one in the Midwest that would include Kentucky.

The IJIS projects are intended to provide the technical design and a working pilot for sharing PMP data among states, but the current pilot will not be completed until early 2007. Kentucky currently has conducted preliminary discussions with Ohio and Indiana PMP officials to begin work on an initiative to establish a PMP data sharing relationship among this small group of states. The intent is to utilize the technical guidelines and formats developed by the IJIS PMP Committee, and to define and implant the processes and agreements for sharing the data that will be consistent with the laws and regulations for each state.

12 Contact Information

12.1 The Cabinet for Health and Family Services

Mark D. Birdwhistle, Secretary

Address: 275 East Main Street
Frankfort, KY 40621
Phone: To contact the Cabinet by phone, you may call the Office of the Ombudsman toll-free at 1-800-372-2973. TTY for hearing impaired; 1-800-627-4702.
Web sites:

Cabinet	http://www.chfs.ky.gov/
Ombudsman	http://www.chfs.ky.gov/omb/
Kentucky Employee Directory	http://phone.ky.gov/

12.2 Office of the Inspector General

Robert J. Benvenuti, III, Esq., Inspector General

Address: 275 East Main Street 5EA
Frankfort, KY 40621
Phone: 502-564-2888
Web site: http://www.chfs.ky.gov/oig/

12.3 Division of Fraud, Waste and Abuse Identification & Prevention

Zachary Ramsey, Director

Address: 275 East Main Street 6EA
Frankfort, KY 40621
Phone: 502-564-5472
Web site: http://www.chfs.ky.gov/oig/dfwaip.htm

12.4 The Drug Enforcement and Professional Practices Branch

David Sallengs, Branch Manager

Address: 275 East Main Street - HS2CB
Frankfort, KY 40621
Phone: 502-564-7985
Web site: http://www.chfs.ky.gov/oig/dfwaip.htm

12.5 KASPER

Hal Rogers Grant Program Administrator: 502-564-1012
KASPER Web site: www.chfs.ky.gov/kasper
KASPER Account Request Web site: https://ekapser.chfs.ky.gov/accessrequest

Appendix A. Doctor Shopper and Diverting Provider Behaviors

A.1 Typical Doctor Shopping Patient Behaviors

While one or even two of these behaviors alone may not be indicative of doctor shopping, three or more of these behaviors should be reason for further inquiry into the patient's controlled substance use.

Patient Behaviors	Examples
Multiple providers of the same type	3 or more general practitioners, dentists, etc.
Dispensers and prescribers are in different localities from each other and the patient's home address	Patient lives in Fayette county; prescriber in Franklin county; dispenser in Jessamine county
Overlapping prescriptions of the same drug from different prescriber types	Oxycodone scripts from dentist, family physician, and pain management doctor within 30 days
Excessive emergency room visits for non-emergency issues	3 or more emergency room visits in a month for chronic pain conditions
Requesting replacement for lost medications regularly	Patient states that controlled substance is lost and requests new prescription
Requesting early refills	Patient requests early refills due to extended out-of-state trip
Pressuring prescribers to prescribe controlled substances for the patient's family members	Patient requests the pediatrician prescribe cough syrup with codeine for their child stating that it is needed for the child to sleep better
Using multiple names, social security numbers, addresses, etc.	Patient fills three scripts under three different names
Seeking referrals to multiple pain management clinics	Patient requests referrals to pain management clinics without a specific diagnosis
Associating with others known to be pharmaceutical controlled substance provider shopping	Patient travels to clinic with another patient exhibiting shopping behavior and requests similar prescription
Self-mutilation	Patient presents with potential self-inflicted wound
Cash transactions	Patient prefers to pay cash when insurance available
Requesting partial dispensing of controlled substance script	Patient requests half of the script and returns for the rest script within 72 hours
After-hour, weekend and holiday calls for prescriptions	Patient calls prescriber at midnight on Friday to request a controlled substance script

A.2 Typical Behaviors of Diverting Providers

If these behaviors are noted for a health care provider, further investigation may be warranted.

Diverting Provider Behaviors	Examples
Migration from general practice to pain management practice	A prescriber licensed as a cardiologist who has changed their practice to pain management patients only
Prescribing outside of the provider's designated specialty	A dentist prescribing diet pills
Excessively high volume of patients	A provider sees excessive number of patients for their specialty
Providers who typically see patients outside of their designated specialty	A cardiologist who sees patients for chronic back pain
Patients are limited to ages 25-40	A pain management physician only sees patients who are 30-35
Prescriptions written for patients who are outside of the typical age range for the designated specialty	An orthodontist who regularly prescribes for seniors
Excessive treatment time in relation to diagnoses	A dentist who prolongs the normal course of treatment for painful procedures such as root canals or extractions
Narcotic prescriptions are a significantly larger percentage of prescriptions in relation to other prescribers in the same specialty	75% of a pediatrician's prescriptions are for a controlled substance
Cash only practice	The practice refuses to accept insurance or any form of payment except cash
Traveling excessively long distances to attend a primary practice	A prescriber lives in Columbus, Ohio and has a primary practice in Lexington, Kentucky
Prescribing for family members or employees	A prescriber writes oxycodone scripts for his/her child who is under the age of 5

Appendix B. Prescription Drug Abuse – Questions and Support Resources

Prescription Drug Abuse
Answers to Your Questions and How to Obtain Help

Misuse, abuse and illegal sale of prescription drugs are some of the largest threats facing the safety and welfare of the citizens of Kentucky. Are you aware of the signs and symptoms of prescription drug problems, and where you can obtain help for you or a loved one?

What is prescription drug abuse?

Although most people use medications as directed, abuse of and addiction to prescription drugs are public health problems for many Kentuckians. Addiction rarely occurs among those who use pain relievers, depressants, or stimulants as prescribed; however, the risk for addiction exists when these medications are used in ways other than as prescribed. Health care providers such as primary care physicians, nurse practitioners, and pharmacists as well as patients can all play a role in preventing and detecting prescription drug abuse.

Is prescription drug addiction a disease?

YES, addiction is a brain disease typically treated with behavioral intervention, drug treatment, or often a combination.

What are the effects of prescription drug abuse?

Prescription drug abuse often causes serious short and long term medical effects which can include:

- Dangerously increased heart rate and blood pressure,
- Hepatitis or AIDS through shared needles
- Violent, erratic, or paranoid behavior and hallucinations,
- Clinical depression,
- Sleeplessness and tremors,
- Liver, lung, and kidney impairment,
- Sudden death (from overdose, heart attack or stroke).

What causes prescription drug abuse?

People use drugs for many reasons, such as:

- Curiosity or experimentation,
- Peer pressure or desire to be part of a group,
- A sense of relaxation and pleasurable euphoria, and
- Numbing effect that helps to ease physical or emotional pain

How can you tell if you or a loved one may be abusing prescription drugs?

As in any disease there are warning signs associated with prescription drug abuse. They typically fall into five categories.

- **Physical:** Fatigue, repeated health complaints, red and glazed eyes, and a lasting cough.

- **Emotional:** Personality change, sudden mood changes, low self-esteem, irritability, irresponsible behavior, poor judgment, depression, general lack of interest.
- **Family:** Starting arguments, breaking rules, withdrawing from the family.
- **School or Work:** Decreased interest, negative attitude, many absences, truancy, visiting many doctors.
- **Social Problems:** New anti-social friends, problems with the law, withdrawal from friends.

What can you do to prevent prescription drug abuse?

There are several ways that patients can prevent prescription drug abuse:

- Provide a complete medical history and a description of the reason for the visit to the health care provider,
- Follow the directions for use carefully and learn about the possible effects of a prescribed drug, especially during the first few days while the body is adapting to the medication,
- Be aware of potential interactions with other drugs by reading all information provided by the pharmacist,
- Do not increase or decrease doses or abruptly stop taking a prescription without consulting a health care provider first, and
- Never use another person's prescription.

Where can you get help for yourself or a loved one?

If you feel that you or a loved one may be a victim of prescription drug abuse or addiction, please speak to a health care provider or contact the **Substance Abuse Hotline at (888) 729-8028.**

What is KASPER and how can it help?

KASPER (Kentucky All Schedule Prescription Electronic Reporting) tracks all controlled substance prescriptions dispensed within the state. Health care providers use **KASPER** to help them identify patients who may be at risk for prescription drug abuse. They review the information on it and if necessary speak to other health care providers who are listed on it.

They do not share the report with other health care providers, the patient, the patient's family, or law enforcement.

What is included in a KASPER report?

A **KASPER** report shows all scheduled prescriptions an individual has had for a specified time period, as well as the doctor who prescribed them and the dispenser who dispensed them.

Four Simple Questions for You and Your Health Care Provider[11]

- Have you ever felt the need to **C**ut down on your use of prescription drugs?
- Have you ever felt **A**nnoyed by remarks your friends or loved ones made about your use of prescription drugs?
- Have you ever felt **G**uilty or remorseful about your use of prescription drugs?
- Have you **E**ver used prescription drugs as a way to "get going" or to "calm down?"

If you need immediate assistance,

contact:

Substance Abuse Hotline
(888)729-8028

Additional Resources for Information and Assistance

Alcoholics Anonymous:
http://www.aa.org/

Center for Substance Abuse Treatment:
http://csat.samhsa.gov/

Drug and Substance Abuse: Signs, Effects and Treatment of Addiction:
http://www.helpguide.org/mental/drug_substance_abuse_addiction_signs_effects_treatment.htm

Kentucky Substance Abuse Treatment Information:
http://mhmr.ky.gov/mhsas/DTX.asp

Narcotics Anonymous:
http://www.na.org/

Support for Friends and Family of Abusers:
http://www.al-anon.alateen.org/

[11] Adapted from Ewing, J.A. "Detecting Alcoholism: The CAGE Questionnaire." *Journal of the American Medical Association* 252(14):1905-1907, 1984.

Appendix C. Status of State Prescription Monitoring Programs

State	Status	Program Ownership	Sched. Covered	Hal Rogers Grants
Alabama	Legislation passed 2004	Dept. of Public Health	II - V	2003,2004,2005
Alaska	Preliminary planning stage			
Arizona	Preliminary planning stage			2005
Arkansas	Legislation in committee	Department of Health	II - V	
California	Implemented	DoJ, Bureau of Narcotic Enf.	II - III	2002,2003,2005
Colorado	Legislation passed. Plan for 2007	Board of Pharmacy	II - V	2004
Connecticut	Legislation in committee	Commissioner-Consumer Prot.	II - V	2004
Delaware	Legislation in committee	Office Narc.& Dangerous Drugs	II - V	
Florida	Plans to reintroduce leg. In 2006	Dept. of Health	II - IV	2003,2004
Georgia	No action			
Hawaii	Implemented	Dept. of Public Safety	II +	2004,2005
Idaho	Implemented	Board of Pharmacy	II - IV	2003
Illinois	Implemented	Dept. Health & Human Svcs.	II	2005
Indiana	Implemented (INSPECT)	Board of Pharmacy	II - V	2004,2005
Iowa	Legislation in committee	State Bd. Pharm. Examiners		2004,2005
Kansas	Preliminary planning stage			2004
Kentucky	Implemented (KASPER)	Cabinet-Health & Family Svcs.	II - V	2002,2004,2005
Louisiana	Resolution passed to study feasibility	Board of Pharmacy		2005
Maine	Implemented	Office of Substance Abuse	II - IV	2003,2004,2005
Maryland	Preliminary planning stage			
Massachusetts	Implemented	Dept. of Public Health	II	2002,2004,2005
Michigan	Implemented	Bureau of Health Professions	II - V	2005
Minnesota				
Mississippi	Implemented	Board of Pharmacy	II - V	2004,2005
Missouri	Hearing conducted	Dept. Health & Senior Services	II - V	2005
Montana	Plans to Introduce Legislation in 2005			
Nebraska	Plans to Introduce Legislation in 2006			
Nevada	Implemented	Board of Pharmacy	II - IV	02,03,04,2005
New Hampshire	Seeking commission to study PMP			2005
New Jersey	Legislation in committee	Div. of Consumer Affairs	II - V	2004
New Mexico	Implemented	Board of Pharmacy	II - IV	2003
New York	Implemented	Dept. of Health	II +	2003,2004,2005
North Carolina	Legislation passed 8/05	Dept. Health & Human Svcs.	II - V	2004
North Dakota	Working group estab. to study PMP	Dept. Human Services		
Ohio	Legislation passed 5/05	Board of Pharmacy	II - V	2002,2005
Oklahoma	Implemented	Bureau of Narcotics	II	2004,2005
Oregon	Legislation in committee	Board of Pharmacy		2004
Pennsylvania	Implemented	Office of the Attorney General	II - IV	2002,2004
Rhode Island	Implemented	Board of Pharmacy	II, III +	
South Carolina	Legislation in committee	Bureau of Drug Control	II - V	2004
South Dakota	Plans to Introduce Legislation in 2005			
Tennessee	Legislation passed 2002	Dept. of Health	II - IV +	2004,2005
Texas	Implemented	Dept. of Public Safety	II	
Utah	Implemented	Board of Pharmacy	II - V	2002
Vermont	Legislation in committee	Dept. of Health	II - IV	2005
Virginia	Leg. Passed 7/05 - expand statewide	Dept. of Health Professionals	II - IV	2002,2004,2005
Washington	Implemented (licensed practitioners)	Dept. of Health	II	2004
West Virginia	Implemented	Board of Pharmacy	II - IV	2002,2004,2005
Wisconsin				
Wyoming	Implemented	Board of Pharmacy	II - IV	2003

Appendix D. KASPER Timeline

1997
Attorney General's Task Force recommends KASPER program

1998
Legislature passes KASPER legislation and Governor signs into law

1999
KASPER program begins in July with 3,105 requests processed in the first six months

2000
KASPER report requests increase to 36,172

2001
KASPER report requests increase to 71,381

2002
KASPER report requests increase to 95,032

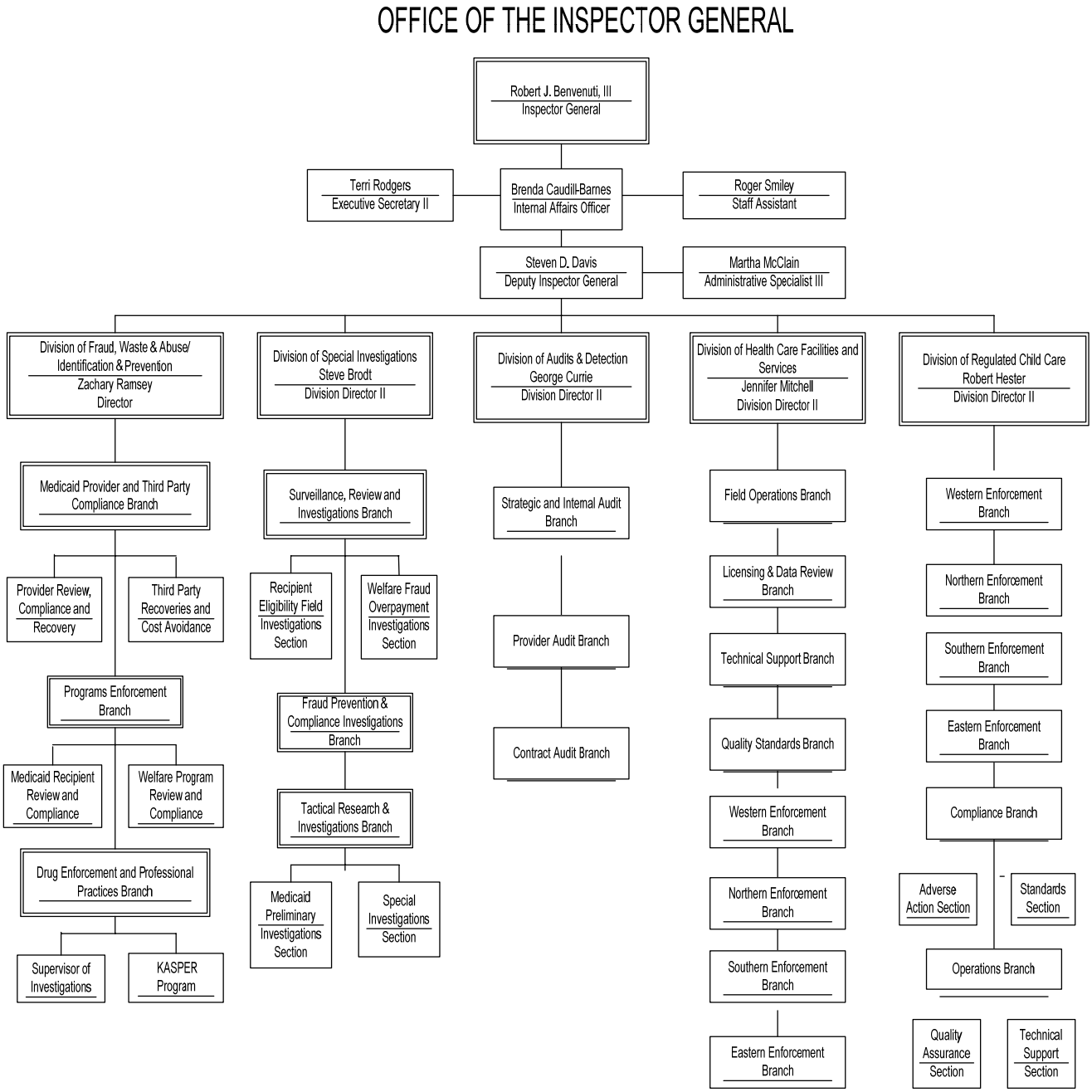
2003
- Development of enhanced KASPER begins after $1.4M funding initiative from legislature
- KASPER report requests increase to 109,442
- Legislative Prescription Drug Abuse Task Force produced a report leading to SB14 making modifications to KRS 218A.202

2004
- Governor Fletcher signs SB14 into law
- Drug Enforcement and Professional Practices Branch moved from the Department for Public Health to the Office of the Inspector General, Division of Fraud, Waste and Abuse/Identification and Prevention
- OIG assumes responsibility for the continued development of eKASPER and administration of the 2004 Hal Rogers Grant
- 2004 Hal Rogers Grant
  - Survey KASPER system users
  - Form focus/work groups to study KASPER
  - Contract with Kentucky Injury Prevention and Research Center to determine effectiveness of KASPER
  - Develop a Medicaid/KASPER interface prototype
- KASPER report requests increase to 122,469

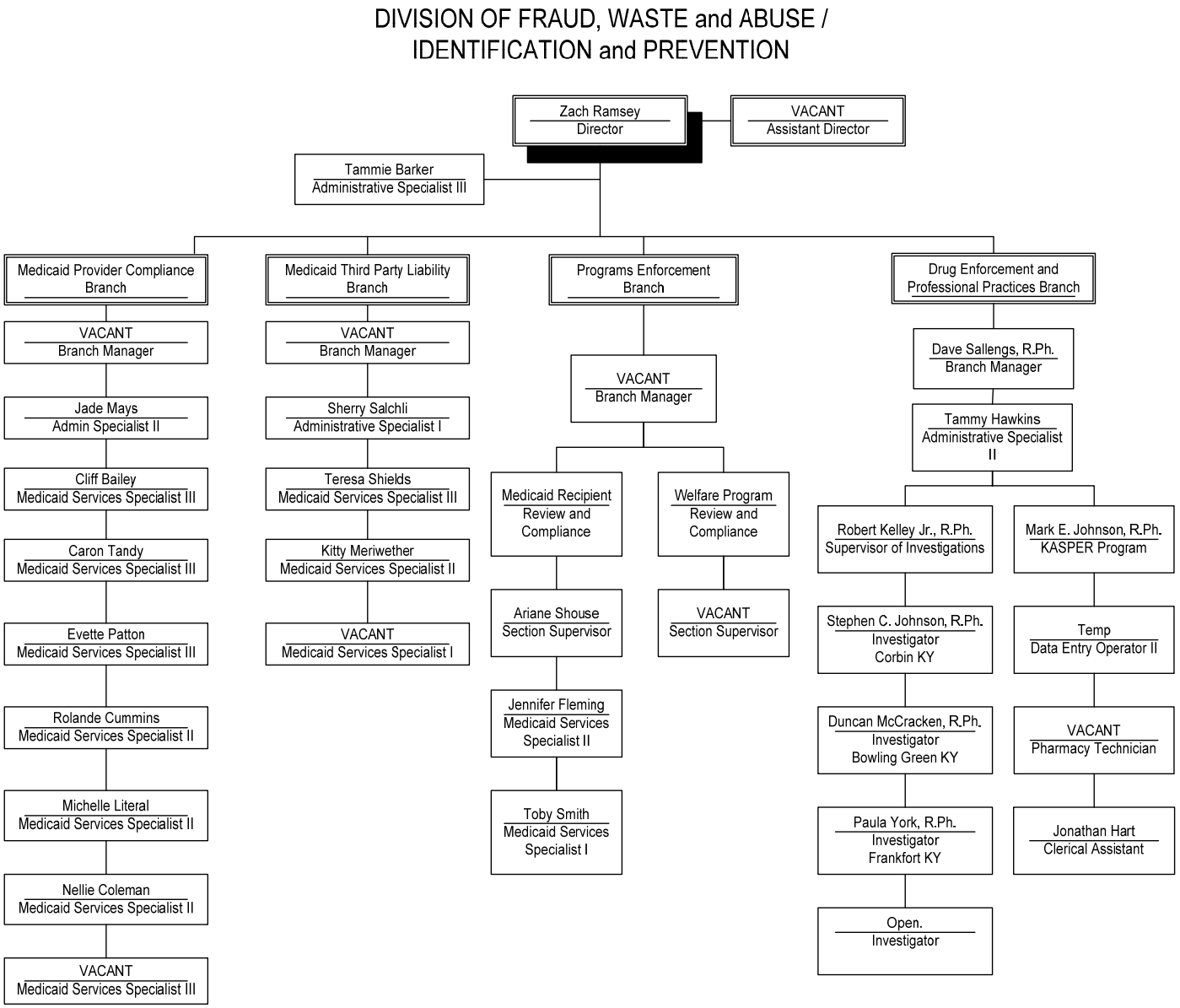
2005
- eKASPER implementation
- 2004 Hal Rogers Grant progress report submitted to DOJ
- 2005 Hal Rogers Grant awarded
  - Continue education and training
  - Develop a means to monitor KASPER system access by users to authenticate user IDs
  - Develop trend reports from KASPER data
  - Streamline KASPER staff business processes to maximize effectiveness

Appendix E. Organization Charts

E.1 Office of the Inspector General



E.2 Division of Fraud, Waste and Abuse Identification & Prevention



Appendix F. OIG Drug Enforcement Investigators

Reprinted from the Kentucky Cabinet for Health and Family Services, CHFS Focus Newsletter, September 12, 2005.

CHFS Focus Employee Spotlight: OIG Drug Enforcement Investigators

Fighting the illegal prescription drug battle

The job on any given day might consist of running down leads for a case, appearing in court, meeting with a prosecutor or drug task force, executing a search warrant, assisting on a police raid, intercepting mail deliveries of illegal prescription drugs or dumpster diving for evidence in Florida. Sound exciting? Well, according to the six drug enforcement investigators with the CHFS Office of Inspector General whose work involves those very activities and more, it is.

Investigators Dave Sallengs, R.Ph.; Bob Kelley, R.Ph.; Duncan McCracken, R.Ph.; Paula York, R.Ph.; and Chris Johnson, Pharm.D., are part of the Drug Enforcement and Professional Practices Branch (DEPPB) in the OIG's Division of Fraud, Waste and Abuse/Identification and Prevention. DEPPB also houses the Kentucky All Schedule Prescription Electronic Reporting (KASPER) program. The job requires the investigators to be registered pharmacists and be vested with police powers.

This group works together to "administer the Kentucky Controlled Substances act as well as parts of the Food Drug and Cosmetics act," Sallengs said. "We are also responsible for licensing manufacturers and distributors shipping controlled substances into Kentucky. We fight the diversion of legally controlled substances every day."

Administrative regulations mandate that investigators must be registered pharmacists with experience working in a retail setting. Kentucky statutes provide the investigators with sworn authority to enforce laws pertaining to drugs in Kentucky. All six investigators, coincidentally, are graduates of the University of Kentucky College of Pharmacy and they all love what they do.

Sallengs, the branch manager, has more than 36 years of experience working with pharmaceutical drugs. Prior to joining the state in 1999, he worked in various pharmacy related fields. "The most rewarding thing about my job is the opportunity to manage such a professional group of people," he said. "In my experience, a person should consider him or herself lucky if he or she looks forward to coming to work every day, and I do."

Kelley is the investigations supervisor and also has 36 years of experience in this area. He became an investigator in 1985 and says he enjoys his job "because of the challenge it presents. Each day is a new adventure and allows me to apply my knowledge and experience. I enjoy working with other law enforcement agencies and meeting new people." Kelley said it gives him a feeling of satisfaction to divert legal controlled substances from being sold and used illegally. "I feel I am doing a great public service," he said.

McCracken became an investigator in 1997. "The most rewarding thing about my job is the knowledge that I am protecting my family and the families of the commonwealth from illegal use and abuse of prescription controlled substances," he said.

York joined the branch as an investigator in 1999. "In my capacity as a pharmacist investigator, I am able to use my pharmacy background in a unique way to help combat the misuse of prescription drugs," she

said. “So many people across Kentucky are impacted in some way by the illegal use of prescriptions drugs and it is very gratifying to know that our office is helping in the fight against prescription drug abuse.”

Johnson became an investigator in 1999. He said he enjoys working with his fellow investigators and other law enforcement agencies. “It takes teamwork to combat the ongoing drug problem in our state,” he said. “There is a certain camaraderie when individuals come together to achieve the same goal.” Johnson considers it an honor to work with various professional licensure boards that play a key role in combating drug abuse by disciplining rogue professionals who work outside the law and pose a danger to themselves and the public.

This small group of investigators keeps busy fighting the illegal prescription drug battle. In June 2004, they were working 209 cases and since that time they have opened 340 new cases and closed 305 cases. Of the closed cases, eight resulted in criminal prosecution; 34 were referred to the Professional Licensure Board for action; seven were sent to Medicaid for further action; 66 were referred to the Attorney General's office for prosecution; 19 went to Commonwealth’s Attorneys offices; two went to the Federal Drug Enforcement Agency; and 136 were sent to state or local police agencies or drug task forces. Thirty three cases were closed without the need for further action.

“This is a group of incredibly well-qualified, conscientious, dedicated and courageous individuals who work hard every day to combat the rising problem of illegal prescription drugs, said Inspector General Robert J. Benvenuti, III. “I am very proud to have them as a part of the OIG and Kentuckians are fortunate to have them as public servants.”

Appendix G. Organizations Associated with Prescription Monitoring Programs

G.1 Hal Rogers Grant Administration

Office of Justice Programs

Since 1984 the U.S. Department of Justice's (DOJ) Office of Justice Programs (OJP) has provided federal leadership in developing the nation's capacity to prevent and control crime, improve the criminal and juvenile justice systems, increase knowledge about crime and related issues, and assist crime victims. Through the programs developed and funded by its bureaus and offices, OJP works to form partnerships among federal, state, and local government officials to control drug abuse and trafficking; reduce and prevent crime; rehabilitate neighborhoods; improve the administration of justice in America; meet the needs of crime victims; and address problems such as gang violence, prison crowding, juvenile crime, and white collar crime. OJP's senior management team—comprised of the Assistant Attorney General, the Deputy Assistant Attorney General, and the five bureau heads—works together with dedicated managers and line staff to carry out this mission.

Bureau of Justice Assistance

The Bureau of Justice Assistance (BJA), Office of Justice Programs, U.S. Department of Justice, supports law enforcement, courts, corrections, treatment, victim services, technology, and prevention initiatives that strengthen the nation's criminal justice system. BJA provides leadership, services, and funding to America's communities by emphasizing local control; building relationships in the field; developing collaborations and partnerships; promoting capacity building through planning; streamlining the administration of grants; increasing training and technical assistance; creating accountability of projects; encouraging innovation; and ultimately communicating the value of justice efforts to decision makers at every level.

G.2 National Associations Promoting or Supporting PMPs

The following associations promote PMPs and/or provide a forum for the establishment of relationships and the exchange of information among member states related to reducing prescription drug abuse and diversion. Kentucky maintains membership status and actively participates in meetings of each of these associations.

The National Alliance for State Model Drug Laws (NAMSDL)

The National Alliance for Model State Drug Laws (the Alliance) is a resource for governors, state legislators, attorneys general, drug and alcohol professionals, community leaders, the recovering community, and others striving for comprehensive and effective state drug and alcohol laws, policies, and programs. The Alliance also provides technical assistance to states that either have a PMP or intend to establish one. The Alliance is the successor of the President's Commission on Model State Drug Laws. Funded by Congressional appropriations since fiscal year 1995, the Alliance is a 501(c)(3) nonprofit, bipartisan organization.

NAMSDL is sponsoring the 3rd National Conference of State Prescription Monitoring Programs on April 12-13, 2006 in Washington D.C. Kentucky has been asked to conduct a presentation on KASPER to the conference participants.

The National Association of State Controlled Substances Authorities (NASCSA)

The National Association of State Controlled Substances Authorities (NASCSA) is a non-profit educational organization. Its primary purpose is to provide a continuing mechanism through which state agencies, federal agencies, the regulated industries and professions, and others can work to increase the effectiveness and efficiency of state and national efforts to prevent and control drug abuse, yet provide mechanisms to make the class of drugs known as controlled substances reasonably available to those persons who have a true medical need for these drugs. This is accomplished by providing a neutral forum during the fall of each year, for the exchange of ideas, information, and views on legal and regulatory issues relating to the controlled substances.

The National Association of Surveillance and Utilization Review Officials

The National Association of Surveillance and Utilization Review Officials (NASO) was begun in 1985 by staff from the various states' Medicaid agencies. The purpose of NASO is to assist states in providing the greatest control of fraud or abuse for the national Medicaid program. Strong program integrity helps assure that Medicaid funds are channeled appropriately to those who need the services.

Kentucky will be hosting the 2006 NASO national conference on August 20-23 in Lexington, KY. The Division of Fraud, Waste and Abuse Identification and Prevention represents the Cabinet for Health and Family Services at NASO, and will be conducting a presentation at the 2006 conference to review how Kentucky has integrated KASPER into the Medicaid support organization and processes, and the planned Medicaid/eKASPER Interface.

The National Association of Drug Diversion Investigators

Established in 1987, the National Association of Drug Diversion Investigators, Inc. (NADDI) is a unique membership organization whose members are responsible for investigating and prosecuting pharmaceutical drug diversion. The organization has proven to be a valuable asset to law enforcement, the pharmaceutical industry and health regulatory personnel. NADDI's objective is simple: to improve the members' ability to investigate, and prosecute, pharmaceutical drug diversion.
NADDI's principle activities are:

1. Cooperative education and training in the specifics of pharmaceutical drug diversion, investigation, prosecution and prevention;
2. Sharing investigative information and communicating with a wide variety of interested parties with regard to the nature, scope and impact of pharmaceutical drug diversion;
3. Developing more effective measures to combat the problem.

Appendix H. KASPER Event Schedule

Event/Organization	Date	Participants/Attendees
Champions Group, Maysville	January 20, 2005 Meeting	
University of Louisville Medical School, Louisville	April 5, 2005	
University of Kentucky School of Pharmacy, Lexington Pharmacy Law Training	April 21, 2005	Approximately 140 students
Boone County Sheriff's Department Meeting	May 11, 2005	
Parole and Probation Office Clerks, Springfield KASPER Training	May 19, 2005	25 parole and probation clerks.
KY Society of Health System Pharmacists, Louisville Trade Show	May 19-20, 2005	86 Pharmacists 40 Technicians 30 Students
KMA Leadership Conference, Louisville Meeting	May 20, 2005	40 participants
Unite Officers, Hazard Meeting	May 25, 2005	
Kentucky Bar Association, Louisville Annual Meeting/Conference	June 8-1, 2005	Conference attendance = 1,488
Trover Clinic, Madisonville KASPER Training	June 9, 2005	Approx. 100 physicians, nurses, and pharmacists in attendence.
KY Coroners, Frankfort KASPER Training	June 14, 2005	24 Coroners in attendence
Hazard Police Meeting	June 17, 2005	
KY Pharmacists Association, Lexington Trade Show	June 23-24, 2005	Approx. 115 pharmacists in attendance.
Boone County Sheriff's Office Meeting	July 27, 2005	
Kentucky State Police Academy, Frankfort KASPER Training	July 27, 2005	71 Cadets
Kentucky Association of Chiefs of Police, Owensboro Meeting	July 27, 2005	
Kentucky State Fair, Louisville Cabinet for Health and Family Services Featured Exhibit	August 22, 2005	Estimated contact with over 1000 fair participants.
Madison County Communities that Care, Richmond KASPER Information Session	August 23-24, 2005	Over 120 health care providers in attendance.
Kentucky State Police Sergeants Meeting General Butler State Park KASPER Training	August 29, 2005	32 KSP Sergeants in attendance.

Event/Organization	Date	Participants/Attendees
Eastern Kentucky Pharmacists Association, Prestonsburg, KY KASPER Training	September 15, 2005	10 pharmacists in attendance.
KY Medical Association, Louisville Annual Meeting/Conference	September 16, 2005	Conference attendance = 734
American Pharmacy Services Corp., Lexington Trade Show	September 17-18, 2005	Estimated 235 conference participants.
State of Florida, Frankfort KASPER Information Session for representatives from the state of Florida.	September 22-23, 2005	3 participants representing the Governor's office and Board of Pharmacy.
Kentucky State Police Special Investigations, Lexington Meeting	September 23, 2005	Approx. 75 KSP participants.
Rotary Club, Richmond KASPER Information Session	September 28, 2005	30 attendees
UK College of Pharmacy ,Lexington KASPER Training	October 6, 2005	Approximately 85 pharmacy students.
Kentucky State Police Academy, Frankfort KASPER Training	October 7, 2005	Approximately 35 cadets.
UK College of Pharmacy, Lexington KASPER Training	October 11, 2005	Approximately 90 pharmacy students.
Lions Club, Stanton KASPER Information Session	October 17, 2005	Approximately 15 attendees.
State Government Bar Association, Frankfort KASPER Information Session	October 25, 2005	Continuing Legal Education for participants
Kentucky Nurses Association, Frankfort Annual Meeting/Conference	October 27-28, 2005	Approx. 180 registered nurses and 276 nursing students.
State of Ohio, Frankfort KASPER Information Session for representatives from the state of Ohio.	November, 2005	Two representatives from the Ohio Board of Pharmacy
Bowen Elementary School – Powell County. Discussion of pharmacy careers and prescription drug use/abuse.	November 2, 2005	Approx. 100 students
State of Louisiana, Frankfort KASPER Information Session for representatives from the state of Louisiana.	November 14-15, 2005	Representatives from the Louisiana Board of Pharmacy and the Louisiana State Police.
UK College of Pharmacy, Lexington KASPER Training	December 5, 2005	Approx. 90 pharmacy students.
University of Kentucky Psychiatry Residents, Lexington KASPER Training	January 11, 2006	18 Psychiatry Residents

Event/Organization	Date	Participants/Attendees
United Healthcare, Lexington KASPER Trend Data	January 20, 2006	Discussion of KASPER trend data and usage to combat prescription drug abuse.
University of Kentucky – Family Practice Residents Pain Management Workshop	January 25, 2006	20 Family Practice Residents
Clinical Applications of the Procedures in Treatment of Addictions and Substance Abuse (CAPTASA) Conference	January 27-28, 2006	420 Conference Participants

Appendix I. Hal Rogers Grant Focus and Working Group Participants

Investigations

Tracy Lutz (Drug Enforcement Administration)
Robert Otero (Drug Enforcement Administration)
Gary Munsie (Kentucky Board of Dentistry)
Marquetta Poynter (Kentucky Board of Dentistry)
Mike Rodman (Kentucky Board of Medical Licensure)
Lloyd Vest (Kentucky Board of Medical Licensure)
Paula Pabon (Kentucky Board of Nursing)
Jeff Osman (Kentucky Pharmacists' Board)
Jerri Robinson (Office of the Inspector General)
Caron Tandy (Office of the Inspector General)
Shoshanna Goldfine (Office of the Inspector General)
Bob Kelley (Office of the Inspector General's Drug Enforcement and Professional Practices Branch)
Christopher Miller (Cabinet for Health and Family Services' Office of Technology)

Trend Reporting

Mike Rodman (Kentucky Board of Medical Licensure)
Lloyd Vest (Kentucky Board of Medical Licensure)
Don Swikert (Kentucky Board of Medical Licensure)
Doug Wilson (Kentucky Board of Medical Licensure)
Caron Tandy (Office of the Inspector General)
Shoshanna Goldfine (Office of the Inspector General)
David Gruneisen (Office of the Inspector General)
Dave Sallengs (Office of the Inspector General's Drug Enforcement and Professional Practices Branch)
Neal Rosenblatt (Cabinet for Health and Family Services' Office of Technology)

Technical Specifications

Randy Gaither (Kentucky Retail Federation)
Lynne Thompson (Office of the Attorney General)
Caron Tandy (Office of the Inspector General)
Shoshanna Goldfine (Office of the Inspector General)
David Gruneisen (Office of the Inspector General)

Intervention

Brian Fingerson (Kentucky Board of Pharmacy)
Heath Dolen (Division of Mental Health/Mental Retardation)
Liz Hornback (KY Board of Medical Licensure)
Karyn Hascal (Office of Drug Control Policy)
Leon Claywell (Kentucky Pharmacists' Association)
Beth Partin (Kentucky Board of Nursing)
Paula Schenk (Kentucky Board of Nursing

Dave Sallengs (Kentucky Drug Enforcement)
Caron Tandy (Office of Inspector General)
Shoshanna Goldfine (Office of the Inspector General)
Neal Rosenblatt (Office of Technology)

Education

After the initial meeting, the Education Working group was split into two subcommittees. The membership of the subcommittees includes all of the members of the full working group.

Marketing Subcommittee

Paul Dassow (University of Kentucky Medical School)
Randy Gaither (Kentucky Retail Federation)
Robert Otero (U.S. Department of Justice)
Beth Partin (Kentucky Board of Nursing)
Brenda Bunting (Kentucky Pharmacists' Association)
Caron Tandy (Office of the Inspector General)
Shoshanna Goldfine (Office of the Inspector General)
Neal Rosenblatt (Office of Technology)

Curricula Subcommittee

Ann Amerson (University of Kentucky)
Brenda Bunting (Kentucky Pharmacists' Association)
Gina Davis (Kentucky Dental Association)
John Firriolo (University of Louisville Dental School)
Mac Bell (Dept. of Mental Health And Mental Retardation)
Robert Otero (U.S. Department of Justice)
Stephen Houghland (University of Louisville Medical School)
Dave Sallengs (Kentucky Drug Enforcement)
Caron Tandy (Office of the Inspector General)
Shoshanna Goldfine (Office of the Inspector General)
Neal Rosenblatt (Office of Technology)

Appendix J. Hal Rogers Grant Performance Measures

The 2005 Hal Rogers Grant included a series of Performance Measures that are to be reported in accordance with the Government Performance and Results Act (GPRA). Following is a summary of the required Performance Measures and the resulting Kentucky reporting as contained in the 2005 Hal Rogers Grant semi-annual progress report for the period July 1 – December 31, 2005.

Performance Measure	Kentucky Results/Status
1. Number of individuals investigated for the diversion of pharmaceutical controlled substances before and after implementation/enhancement of the program.	We do not currently have this data available on a statewide basis, due to the diverse number of law enforcement agencies investigating diversion cases. We are planning to work with the Office of Drug Control Policy (ODCP) to review how we can obtain this data. Following is the data for the Drug Enforcement and Professional Practices Branch (DEPPB). 2004 Investigations = 247 2005 Investigations = 593
2. Number of individuals arrested for the diversion of pharmaceutical controlled substances before and after implementation/enhancement of the program.	We do not currently have this data available on a statewide basis due to the diverse number of law enforcement agencies investigating diversion cases. We are planning to work with ODCP and DEPPB to review how we can obtain this data.
3. Number of individuals prosecuted for the diversion of pharmaceutical controlled substances before and after implementation/enhancement of the program.	We do not currently have this data available on a statewide basis due to the diverse number of law enforcement agencies investigating diversion cases. We are planning to work with ODCP and DEPPB to review how we can obtain this data.
4. Number of dosage units of pharmaceutical controlled substances diverted by individuals who have been prosecuted. (Indicates focus has been placed on high-level diverters rather than low-level individuals.)	We do not currently have this data available on a statewide basis due to the diverse number of law enforcement agencies investigating diversion cases. We are planning to work with ODCP and DEPPB to review how we can obtain this data.
5. Number of Emergency Room and/or Medical Examiner reports of adverse events before and after implementation/enhancement of the program.	We are working with the Kentucky Injury Prevention Research Center to collect and analyze this data. Currently we have established the following baseline data. Hospitalizations for Intentional Drug Overdoses: 2000 = 1,741 2001 = 2,021 2002 = 2,234 Hospitalizations for Unintentional Drug Overdoses: 2000 = 749 2001 = 985 2002 = 951 We plan to work with KIPRC to identify this data for 2003 and 2004 along with other key prescription drug related data, and to begin analyzing the data for trends reflecting the impact of increasing usage of KASPER.

6. Number of excessive prescriptions for controlled substances from multiple prescribers obtained by "doctor shoppers" (individuals identified as receiving an excessive number of prescriptions) before and after such identification.	We do not currently have defined thresholds for identifying doctor shopping, but are working with the NASCSA committee attempting to define consistent doctor shopping thresholds among the states. Once these thresholds are established we will plan to report this data.
7. Number of unsolicited notices sent to practitioners by the monitoring program.	Kentucky Statutes do not currently provide for sending unsolicited notices or reports to practitioners. Kentucky does provide unsolicited trend reports that do not identify an individual prescriber, dispenser or patient to our regulatory agencies.
8. Number of reports requested by practitioners.	Following are the number of KASPER reports produced by year. 2000 = 36,172 2001 = 71,381 2002 = 95,032 2003 = 109,442 2004 = 122,469 2005 = 186,279 The figure for 2005 reflects the March 2005 implementation of eKASPER (the Web-based version of KASPER). Of these reports, approximately 90% were requested by health care practitioners.
9. Number of investigations completed per investigator per year before and after implementation/enhancement of the program.	We do not currently have this data available on a statewide basis due to the diverse number of law enforcement agencies investigating diversion cases. We are planning to work with ODCP and DEPPB to review how we can obtain this data.
10. Average number of work hours/days spent per case before and after implementation/enhancement of the program.	After implementation of KASPER, the average age of “doctor shopper” cases under internal investigation dropped from 156 to 19 days.
11. Number of reports disseminated to out-of-state regulatory agencies regarding filled prescriptions written by practitioners from another state.	A small number of reports have been provided to out-of-state regulatory agencies on an ad hoc basis. We do not have the exact number of reports provided. We plan to determine the feasibility of obtaining this data from the system, and to provide the data in the next progress report if possible.
12. Number of joint investigations conducted.	We do not currently have this data available on a statewide basis due to the diverse number of law enforcement agencies investigating diversion cases. We are planning to work with ODCP and DEPPB to review how we can obtain this data.
13. Average number of days between the date a prescription is filled and the date the data is available in the system.	Based upon the regulatory reporting requirements for dispensers, and the processing time for our data collection contractor, prescription data is normally available in KASPER 30 to 45 days after the date of dispensing. The Office of the Inspector General is proposing a regulation change that will reduce the data availability to 15 to 30 days.

14. Length of time required to provide reports pertaining to suspect activity to requestor (practitioner, pharmacist, regulatory or law enforcement agency).	For fax based report requests the average time to obtain a report is approximately one day. For report requests through eKASPER the average time to obtain a report is less than 15 minutes, with many reports available within 15 to 20 seconds.